UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA, STATES OF CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW HAMPSHIRE, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VERMONT, WASHINGTON, and the COMMONWEALTHS OF MASSACHUSETTS, PUERTO RICO, VIRGINIA and the DISTRICT OF COLUMBIA, *ex rel.* JOHN COLLADO,

Plaintiff-Relator,

v.

BRACCO USA, INC., BRACCO DIAGNOSTICS, INC., ACIST MEDICAL SYSTEMS, INC., NYU LANGONE HEALTH SYSTEM, INC., DUPAGE MEDICAL GROUP, HONORHEALTH, SOUTHERN ILLINOIS HEALTHCARE ENTERPRISES, INC., UNIVERSITY OF NEBRASKA, and JOHN DOE DEFENDANTS 1-100,

Defendants.

Hon. Julien X. Neals

Civil Action No. 20-8719

AMENDED COMPLAINT

DEMAND FOR JURY TRIAL

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On behalf of the United States of America ("United States") and the States of California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Louisiana, Michigan, Minnesota, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Vermont, Washington and the Commonwealths of Massachusetts, Puerto Rico, Virginia and the District of Columbia, (collectively, the "Government"), Plaintiff-Relator John Collado, ("Plaintiff-Relator," or "Relator"), by and through the undersigned counsel, files this *qui tam* Complaint against Defendants Bracco USA, Inc., Bracco Diagnostics, Inc., Acist Medical Systems, Inc., their parents and subsidiaries operating in the United States, also known as the Bracco Group (collectively, "Bracco"), and NYU Langone Health System, Inc. ("NYU Langone"), DuPage Medical Group, Inc. a/k/a DuPage Medical Group, Ltd. d/b/a Duly Health and Care ("DuPage"), HonorHealth, Southern Illinois Healthcare Enterprises, Inc., ("Southern Illinois Health"), the University of Nebraska ("UNebraska") and John Doe Defendants 1-1000 (collectively, the "Provider Defendants,") (altogether, the "Defendants"), alleging as follows:

I. INTRODUCTION

1. This is a civil fraud action filed by *qui tam* Relator against Defendants, for violations of the federal Anti-Kickback Statute, 42 U.S.C. §1320a-7b, *et seq*. (the "Anti-Kickback Statute" or "AKS"), the False Claims Act (the "FCA"), 31 U.S.C. §§ 3729, *et seq.*, and the various False Claims Acts of the States of California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Louisiana, Michigan, Minnesota, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Vermont, Washington and the Commonwealths of Massachusetts, Puerto Rico, and Virginia and the District of Columbia arising from the sale of imaging agents – contrast media

products – used in the field of radiology.

2. Contrast media products, also known as contrast media agents or imaging agents, are used in medicine to enhance the blood and body tissues of patients for medical imaging radiology, such as x-rays, CT scans, MRIs and ultrasound. Approximately, 400 million radiology tests are performed in the United States every year; and the United States spends about $100 billion on radiology testing annually.

3. Originally, imaging agents were injected into the body manually, using a hand-held syringe. Today, imaging agents are administered using electronic power injector systems to control administration characteristics like volume, flow speed and pressure during medical imaging.

4. Bracco manufactures imaging agents and related products for sale in the U.S. and abroad; its products are used for x-ray imaging, computed tomography ("CT") scans, magnetic resonance imaging ("MRI"), contrast enhanced ultrasound ("CEUS"), and nuclear medicine through radioactive tracers; Bracco also manufactures the medical devices, power injectors and injection systems, used to administer imaging agents to patients ("power injectors") in the field of radiology.

5. Bracco sells imaging agents to hospitals and medical facilities throughout the United States, including but not limited to NYU Langone, DuPage, HonorHealth, Southern Illinois Health, and UNebraska. NYU Langone is one of the nation's premier teaching hospitals with six facilities located in New York City. DuPage operates physician offices and urgent care centers in Illinois. HonorHealth is a system of hospitals and care centers in Arizona. Southern Illinois Health is another hospital system in south Illinois affiliated with the medical school at Southern Illinois University. UNebraska is comprised of four university campuses including the Medical Center in

Omaha which trains doctors, performs research, and is affiliated with an approximately 700-bed teaching hospital.

6. Together, Defendants are engaging in a kickback scheme to induce the sale and purchase of Bracco's imaging agents and related products with the supply of ***free*** power injector equipment; defendants have also agreed to conceal their transactions from the Government; and to file false claims for reimbursement or cause them to be filed.

7. Defendants' schemes involved entering into sham contracts for fictitious "leases" of free power injector equipment sometimes described as "royalty-free" leases or "discounts" on the sale of imaging agents; these written agreements are used to disguise the kickback scheme; at the same time Defendants agreed to skirt their transparency, price and cost reporting obligations; and Defendants subsequently filed or caused false claims to be filed for radiology services performed with imaging agents purchased via their kickback scheme. Such claims seek reimbursement for imaging agents bought with kickbacks.

8. Defendants' claims for reimbursement for radiology services and for imaging agents purchased as a result of illegal kickbacks constitutes a fraud upon Medicaid, Medicare, Tricare and other government health programs, which have paid significant funds for such services and imaging agents for their members.

9. This kickback scheme increased Bracco's sales of imaging agents annually. As a result of this nationwide scheme, Bracco has violated and continues to violate the False Claims Acts and reap profits far beyond those it could achieve from legitimate sales. The Provider Defendants also benefited from the receipt of free equipment reducing their operating costs which go unreported to the Government and fraudulently inflate their claims for reimbursements.

10. This action seeks treble damages and civil penalties on behalf of the Government from Defendants for knowingly and/or recklessly presenting or causing to be presented such false claims to the Government in violation of the FCA, 31 U.S.C. §§ 3729, *et seq.*, and applicable regulatory guidance in order to illegally increase the sales of Bracco imaging agents. The illegal acts alleged herein were personally witnessed by Relator while he worked for a competitor of Bracco and began at least as early as 2016, and continue through the present (the "Covered Period").

11. Defendants knowingly made and/or caused to be presented false and/or fraudulent claims, records, and/or statements to the Government in connection with the receipt of reimbursements from the Centers for Medicare and Medicaid Services ("CMS"). The claims, records and/or statements were false and/or fraudulent because they were tainted by illegal kickbacks in the form of free medical equipment given by Bracco to the Provider Defendants in exchange for purchasing 90% of the imaging agents they use from Bracco on a regular basis for a number of years.

12. Moreover, Defendants did not report the placement of the equipment to CMS as required under the Physician Payment Sunshine Act, Section 6002 of the Patient Protection and Affordable Care Act (the "Sunshine Act"), and misrepresented prices and costs in Medicare required reports to CMS.

13. Defendants' false claims, records, and/or statements caused CMS to make millions of dollars of overpayments to Defendants under Medicaid, under Medicare Parts A & B, as under other Government Programs. Additionally, with knowledge that the claims were false when submitted, Defendants failed to notify the Government of the false claims and resulting overpayments, or to return such overpayments. *See* 42 C.F.R. § 422.326.

14. Defendants have committed various types of fraud against Medicaid, Medicare, and other Government Payors (collectively, "Government Programs"). These types of fraud include a kickback scheme to induce purchases of imaging agents, concealment of the scheme through fraudulent contracting and reporting, and submission of legally false claims for reimbursement tainted by kickback violations.

15. As a result of these improper practices, thousands of false claims were submitted to Government Programs during the Covered Period. Defendants' schemes caused Government Programs to pay reimbursements to Defendants that would not have been paid but for Defendants' illegal conduct, which is specifically prohibited by federal and state law, regulations, and policies.

16. Defendants have actual knowledge that they are engaging in illegal conduct in the form of a kickback scheme, concealing it by ignoring their reporting obligations or by filing false cost or pricing information with the Government, and by profiting with the filing of false claims for imaging agents and related radiological services tainted by kickbacks; such claims are not entitled to payment and such improperly obtained payments must be refunded to the Government. Defendants have chosen to profit from fraudulently billing Government Programs instead of disclosing the true nature and extent of their transactions and the kickbacks paid to drive sales.

II. PARTIES

A. Relator's Background

17. Plaintiff-Relator John Collado is a citizen of the United States and a resident of the State of New York.

18. Relator is presently employed by Philips Healthcare as a sales agent. Previously, he worked for Bayer's Radiology/Interventional Division, in Wayne, New Jersey, since May 2005. At Bayer, Relator was an Executive Sales Consultant responsible for sales of software and imaging injectors to hospitals, radiologists, cardiologists, neurologists, vascular surgeons, nuclear medicine

specialists and physicists. Relator sold over $106 million in total goods and services during his career with Bayer. Previously, Relator worked as a sales consultant for Ricoh in high volume print and copying from 2002 to 2005; he also worked as an account manager for Sun Microsystems computer company, in the area of servers and data storage, from 1998 to 2002; and he worked as an account representative for Xerox from 1989 to 1998. He possesses a Bachelor of Arts degree from Fordham University.

19. Throughout his career, Relator developed numerous contacts with purchasing agents in the healthcare industry. Through these contacts and his investigations, Relator learned that Bracco turned to illegal kickbacks in order to increase its United States sales of imaging agents and related products for X-ray, CT, MRI, CEUS and nuclear medicine (the "Contrast Media Products") and injector disposable products (the "Consumables") used in performing such imaging services (together "Bracco Products"). Relator has confirmed that NYU Langone, DuPage (through contracts entered into by Meridian Medical Associates and Pronger Smith Med Care and assumed by DuPage), HonorHealth, Southern Illinois Health, and UNebraska have conspired to accept such kickbacks in exchange for reduced equipment costs.

20. Relator personally witnessed and gained direct and independent knowledge of the information on which the below allegations are based, and Relator has voluntarily disclosed such information to the Government pursuant to 31 U.S.C. §3730(e)(4)(B)(i). To the extent any of Relator's allegations have been publicly disclosed as contemplated by 31 U.S.C. §3730(e)(4)(A), Relator is an original source and Relator's knowledge is independent of and materially adds to those allegations pursuant to 31 U.S.C. §3730(e)(4)(B)(ii).

B. Background on Defendants

21. Bracco USA, Inc. has approximately 380 total employees across all of its locations and generates $176.03 million in sales (USD) and is headquartered in Monroe Township, NJ.

22. Bracco Diagnostics, Inc. has approximately 375 total employees across all of its locations and generates $167.37 million in sales (USD) and is headquartered in Monroe Township, NJ.

23. ACIST Medical Systems, Inc. has approximately 360 total employees across all of its locations and generates $160.00 million in sales (USD).

24. These Defendants are known as "The Bracco Group," an Italian multinational healthcare company headquartered in Milan, with approximately 115 companies in the corporate family, more than 3,300 employees worldwide and revenues of €1.3 billion in over 90 markets. These Defendants describe themselves as being committed to the discovery, development, manufacturing and marketing of imaging agents and solutions aimed at providing a better use and management in terms of diagnostic efficacy, patient safety and cost effectiveness.

25. Bracco develops and commercializes imaging agents for use in all types of radiology. Its global headquarters are located in Milan, Italy and its United States operations are headquartered in Monroe Township, New Jersey and Eden Prairie, Minnesota.

26. NYU Langone is one of the nation's premier medical centers. Based in Manhattan, NYU Langone boasts six inpatient locations across New York City offering a broad range of specialized services, including neonatal intensive care, state of the art surgical care and diagnostic technology, orthopedics, pediatrics, a teaching hospital and trauma center, and one of the top rehabilitation centers in the country. NYU Langone has reported annual revenue of $2.26 billion.

27. DuPage Medical Group, Inc. a/k/a DuPage Medical Group, Ltd., which may also

operate under the trade name of Duly Health and Care, located at 1100 W. 31st Street, Suite 300, Downers Grove, Illinois 60515, and successor in interest to Meridian Medical Associates and Pronger Smith Med Care, with locations at 2100 Glenwood Avenue, Joliet, Illinois 60435 and 17495 La Grange Road, Tinley Park Illinois 60487 respectively, was formed in 1999 when three healthcare groups serving the western suburbs of Chicago since 1960 joined together. Today, DuPage, which recently rebranded itself as Duly Health and Care, has grown into the largest and most successful independent multi-specialty physician group in Illinois. DuPage has over 6,000 employees, 150 locations and $1 billion in revenue in 2020.

28. HonorHealth is a nonprofit healthcare system comprised of five hospitals serving Phoenix and Scottsdale, Arizona, and over 70 primary, specialty, and urgent care facilities (e.g., surgery, pediatrics, oncology) throughout the state. HonorHealth is associated with more than 3,400 expert physicians and employs 11,600 dedicated employees. HonorHealth has reported approximately $1.82 billion in annual revenue.

29. Southern Illinois Health is a nonprofit health care system operating a 145-bed tertiary-care Memorial Hospital of Carbondale, the 114 bed Herrin Hospital and St. Joseph Memorial Hospital (with 25 beds) providing services such as birthing, cardiac, cancer, and emergency care, as well as surgery and rehabilitation to residents in Southern Illinois. Southern Illinois Health is also affiliated with the Prairie Heart Institute at St. John's Hospital in Springfield, Illinois and the medical school at Southern Illinois University conducts its Family Practice Residency Program at Memorial Hospital of Carbondale. Southern Illinois Health has reported annual revenue of $685 million.

30. UNebraska is comprised of four university campuses throughout the State of Nebraska. Founded in 1869, the University confers Bachelor's, Master's, and Doctoral degrees in

more than 170 majors including agriculture, business, education, and engineering at its campuses in Kearney, Lincoln, and Omaha. The University's Medical Center is located in Omaha and trains doctors, performs research, and is affiliated with an approximately 700-bed teaching hospital. The school also operates research and extension services across the state. UNebraska has reported annual revenue of $1.2 billion.

31. John Doe Defendants 1-1000 are persons or entities doing business with Bracco under the same or similar schemes and agreements alleged herein. Bracco operates throughout the United States, and markets and sells it's imaging agents and associated devices through a network of sales agents, wholesalers and distributors. Relator believes that Bracco is conspiring with numerous customers throughout the United States in the same or similar manner alleged herein and intends to, and reserves the right to, amend this Complaint to join these John Does upon discovery.

III. JURISDICTION AND VENUE

32. This Court has subject matter jurisdiction over Relator's FCA and AKS claims. The United States District Courts have exclusive jurisdiction over actions brought under the FCA pursuant to 31 U.S.C. § 3732, and otherwise have jurisdiction over federal statutory causes of action under 28 U.S.C. § 1331 and 1345. This Court has jurisdiction over Relator's state and common law claims pursuant to 28 U.S.C. § 1367.

33. Jurisdiction and venue are proper in this Court pursuant to the False Claims Act, 31 U.S.C. § 3732(a), because Relator's claims seek remedies on behalf of the United States for multiple violations of 31 U.S.C. § 3729, *et seq*. in the United States by all or any one of the Defendants, some of which occurred in the District of New Jersey, and because Defendant

Bracco, the mastermind of the scheme alleged here, transacts business within the District of New Jersey and at least two of its American business units are headquartered in New Jersey.

34. All Defendants are subject to the general and specific jurisdiction of this Court.

35. As a result of Bracco's organizational structure, Bracco, S.p.A. and Bracco Imaging S.p.A. have continuous and systematic contacts with the United States through their contacts and control over their American subsidiaries.

36. This Court also has jurisdiction over actions brought under the laws of the various states since this action arises from the same transactions or occurrences. 31 U.S.C. § 3732 (b).

37. Under the FCA and the State FCAs, this Complaint is to be filed *in camera* and remain under seal for at least 60 days unless the Court orders otherwise.

IV. RESPONDEAT SUPERIOR AND VICARIOUS LIABILITY

38. Any and all acts alleged here to have been committed by any or all of the Defendants were committed by said Defendants' officers, directors, employees, representatives or agents who at all times acted on behalf of their respective Defendant(s) and within the course and scope of their employment.

39. The Bracco Defendants are related entities sharing common employees, offices and business names such that they are joint and severally liable under legal theories of *respondeat superior*. Further, the past, present and continuing relations and dealings by and between these related entities are so inextricably intertwined that for purposes of this suit, some or all of them can and should be considered as a single entity at law and equity.

40. The Bracco Group engages in a variety of business activities, including developing, marketing, and selling contrast media agents, all of which is, or was, accomplished through Bracco's operating groups, subsidiaries, officers, directors, employees, and agents. Bracco's

subsidiaries include holding companies, operating groups and regional companies, for the most part generally organized by location, including companies operating throughout the United States. The functions of these operating groups and regional companies overlap.

41. Bracco Diagnostics, Inc., established in 1994, is an American, wholly-owned subsidiary of Bracco Imaging S.p.A., established in 1985, and part of the Bracco Group, which oversees and coordinates the activities of Bracco's business all over the world, including in the United States. For example, Bracco Diagnostic Inc.'s website contains local and worldwide contacts; its press room page contains press releases about other Bracco Group members which state that the media and investors may contact company personnel abroad and in the United States.

42. Thus, Bracco S.p.A. and Bracco Imaging S.p.A. approve and direct the marketing activities of Bracco's subsidiaries in the United States.

V. RELEVANT STATUTORY SCHEMES

A. The FDA's Role in the Regulation of Imaging Agents

i. FDA Approval of Imaging Agents and Injection Devices

43. The FDA regulates use of imaging agents and the medical devices used to administer them. Medical imaging agents are generally governed by the same regulations as other drugs and biological products.

44. Companies seeking to introduce new imaging agents and associated devices for human use into interstate commerce must comply with FDA statutes and regulations, such as the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301, *et seq*. The FDCA prohibits companies from distributing in interstate commerce any drugs, including imaging agents that the FDA has not approved as safe and effective. 21 U.S.C. § 355(a) and (b).

45. In order for a company to gain approval of an imaging agent by the FDA, the company must first submit and receive approval of a New Drug Application ("NDA") pursuant to

21 U.S.C. § 355. The company is required to include in its NDA all intended uses proposed for a new imaging agent's labeling and to prove the new imaging agent is safe and effective for those uses. 21 U.S.C. § 355(b). To prove that the imaging agent is safe and effective, the company must provide the FDA with data from scientifically sound clinical trials. The FDA will refuse approval of a new imaging agent unless, on the basis of all information reviewed, it is demonstrated that the imaging agent can safely accomplish its purported effect under the conditions proposed, and that the method of manufacture and distribution will properly preserve the agent for this purpose. 21 U.S.C. § 355(d).

46. The FDCA provides for approval of medical devices, including imaging agent injectors. 21 U.S.C. § 321(h). Under the current framework the Center for Devices and Radiological Health ("CDRH") has primary jurisdiction over medical devices. 21 C.F.R. 3.5. Medical devices are classified into three categories based on the risk they pose to the public: Class I devices are low-risk, Class II devices are potentially more harmful, and Class III devices are high-risk. 21 U.S.C. § 360c. FDA determines the safety and effectiveness of devices (a) with respect to the persons for whose use the device is represented or intended, (b) with respect to the conditions of use prescribed, recommended, or suggested in the labeling of the device, and (c) weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from such use. 21 U.S.C. § 360c. Injectors are routinely classified as Class II devices.[1]

[1] *See e.g.* https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?start_search=201&Submission_Type_ID=&DeviceName=&ProductCode=&DeviceClass=&ThirdParty=&Panel=CV&RegulationNumber=&PAGENUM=25&SortColumn=RegulationNumberDESC.

B. Reimbursement of Contrast Media Agents under Medicaid, Medicare Part A and Part B, CHAMPUS/TRICARE, CHAMPVA, FEHBP, and Other Federal Healthcare Programs

i. Medicaid

47. As a general rule, to be reimbursable under a state's Medicaid program, a drug – including contrast media agents – must be included on the state's formulary. Each state has its own means of deciding coverage, but federal law sets forth requirements states must meet in excluding or restricting coverage. *See* 42 U.S.C. § 1396r--8. A state may exclude or restrict coverage of a drug in four instances:

> (1) the prescribed use is not for a medically accepted indication;
> (2) the drug is on the list of drugs excluded by the state from Medicaid coverage;
> (3) the drug manufacturer agreed to the restrictions on the drug in its rebate agreement with Medicaid; and
> (4) the drug was excluded from state's drug formulary.

42 U.S.C. § 1396r-8(d)(1). In addition, states may use prior authorization programs or preferred drug lists to control potential abuses of drugs, such as prescriptions for an indication that is not a medically accepted indication.

48. A "medically accepted indication" is a use that is listed in the labeling approved by the FDA or "the use of which is *supported by* one or more citations included or approved for inclusion in" one of the drug compendia identified by the Medicaid statute. 42 U.S.C. § 1396r-8(k)(6) (emphasis added). These compendia are the American Hospital Formulary Service Drug Information, the United States Pharmacopeia-Drug Information (or its successor publications), and the DRUGDEX Information System. 42 U.S.C. § 1396r-8(g)(l)(B)(i). The United States Government and the states interpret "supported by" to require "some form of corroboration or validation." United States' Statement of Interest in Response to Defendant's Motion to Dismiss Plaintiffs First Amended Complaint, *United States ex rel. Rost v. Pfizer, Inc.*, 03-CV-11084, at p.

5 (D. Mass. May 16, 2008); *see also* Centers for Medicare and Medicaid Release No. 141 (May 4, 2006) ("The statute requires coverage of off-label uses of FDA-approved drugs for indications that *are supported (as opposed to listed)* in the compendia specified in section 1927(g)(l)(B)(II).") (emphasis added).

49. States may establish drug formularies if they meet the requirements under 42 U.S.C. § 1396r-8(d)(4). The formulary must be developed by a committee consisting of pharmacists, physicians and other qualified individuals appointed by the governor or by the state's Drug Use Review ("DUR") board consisting of healthcare professionals who have recognized knowledge and expertise in the prescription, dispensing and monitoring of outpatient drugs, drug use review, and medical quality assurance. 42 U.S.C. § 1396r-8(d)(4)(A) and § 1396r-8(g)(3). Imaging agents, such as Bracco's Isovue, are routinely included in state drug formularies.

50. The formulary must include every drug for which a manufacturer has entered into a Medicaid rebate agreement. 42 U.S.C. § 1396r-8(d)(4)(B). The state may, however, exclude a drug from the formulary if: (1) the drug is used for an on-label use -- or an off-label use that is a medically accepted indication based on compendia -- but the drug does not have a significant, clinically meaningful therapeutic advantage over other drugs on the formulary; and (2) the state provides a written explanation, which is available to the public, of why the drug is excluded. 42 U.S.C. § 1396r-8(d)(4)(C). Finally, any drugs excluded from the formulary must nevertheless be available to Medicaid enrollees under a prior authorization program. 42 U.S.C. § 1396r-8(d)(4)(D).

51. States generally have some method for drug manufacturers to request that its drug be added to the states' "preferred drug lists." In the majority of states, the Pharmaceutical and Therapeutics committee or the DUR board make the decision on whether to add drugs to the state

Medicaid program's preferred drug list. Generally, these committees announce that they will conduct a review of a class of drugs. At that time, a drug manufacturer may submit information to the committees to be considered for the drug list. A minority of states, such as Indiana, Montana, Nevada and Texas, require drug manufacturers to submit an application to be placed on the drug list. As part of the Texas application, drug manufacturers are required to expressly certify compliance with all laws, regulations and rules applicable to the Medicaid program, including the federal and state Anti-Kickback statutes. The Standard Medicaid Provider Agreement, the Standard Medicare Provider Agreement and Health Insurance Claim Form 1500, used for submission of Medicaid, Medicare, and TRICARE/CHAMPUS claims also requires compliance with "all applicable Medicare and/or Medicaid laws, regulations and program instructions for payment including but not limited to the Federal anti-kickback statute." *See* https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS1500.pdf.

52. Pharmaceutical Therapeutics Committees and DUR boards are required to continually "assess data on drug use against predetermined standards," using the compendia as the source for these standards. 42 U.S.C. § 1396r-8(g)(l) and (2). These standards include but are not limited to monitoring for therapeutic appropriateness, overutilization and underutilization, appropriate use of generic products, drug-drug interactions. *Id*. The States' continual assessment of drug data permits them the flexibility to determine the appropriate scope, duration, and limitations on coverage of drugs on their formularies.

ii. Medicare Part A and Medicare Part B

53. Medicare Part A is a federal program that covers inpatient care, including care received while in a hospital, a skilled nursing facility or hospice, and, in limited circumstances at home. *See generally* 42 U.S.C. §§ 1395c through 1395i-5.

54. Medicare Part A statutes can be found at 42 U.S.C. §§ 1395c, *et seq*. and the regulations are located at 42 C.F.R. Part 400. The policy manuals can also be found at www.cms.gov/regulations-and-guidance/guidance/manuals/internet-only-manuals-ioms-items/cms018912.html

55. Medicare Part A is generally available to individuals who are age 65 or over and are eligible for retirement benefits under certain federal requirements. *See* 42 USCS § 1395c.

56. The Government periodically determines the amount which should be paid under Medicare Part A [42 USCS §§ 1395c, *et seq*.] to each provider of services with respect to the services furnished by it, and the provider of services shall be paid, at such time or times as the Secretary of Health and Human Services believes appropriate (but not less often than monthly) and prior to audit or settlement by the General Accounting Office (GAO), from the Federal Hospital Insurance Trust Fund, the amounts so determined, with necessary adjustments on account of previously made overpayments or underpayments; except that no such payments shall be made to any provider unless it has furnished such information as the Secretary may request in order to determine the amounts due such provider under Medicare Part A [42 USCS §§ 1395c, *et seq*.] for the period with respect to which the amounts are being paid or any prior period. 42 USCS § 1395g.

57. Medicare Part B is a federal program meant to subsidize the costs of medically necessary services such as doctors' services, some preventative services, ambulance services, durable medical equipment and outpatient care. Part B also covers diagnostic imaging and contrast agents. Part B also provides supplemental benefits to participants to cover, among other things, prescription drugs. *See generally* 42 U.S.C. §§ 1395j-l395w-6.

58. Medicare Part B statutes can be found at 42 U.S.C. §§ 1395j–1395w-6 and the regulations are located at 42 C.F.R. Part 414. The policy manuals can also be found at

https://www.cms.gov/regulations-and-guidance/guidance/manuals/internet-only-manuals-ioms-items/cms018912.html

59. Medicare Part B was designed to create supplementary medical insurance for aged and disabled individuals who elect to enroll under this voluntary program, to be financed from premium payments by enrollees together with contributions from funds appropriated by the Federal Government. 42 U.S.C. § 1395j and § 1395l.

60. Every individual who is entitled to hospital insurance benefits under Medicare Part A, 42 U.S.C. §§ 1395c, *et seq.*, or has attained age 65 and is a resident of the United States, and is either a citizen or an alien lawfully admitted for permanent residence who has resided in the United States continuously during the 5 years immediately preceding the month in which he applies for enrollment under Part A, 42 U.S.C. §§ 1395j, *et seq.*, is eligible to enroll in Medicare Part B.

61. Administration of Medicare Part B is conducted through contracts with Medicare administrative contractors. 42 U.S.C. § 1395u. Additionally, the Federal Government may enter into an agreement with a state pursuant to which all eligible individuals in either of the coverage groups will be enrolled under Medicare Part B. 42 U.S.C. § 1395v.

62. Under Medicare Part B, reimbursement is prohibited if the item or service is not "reasonable and necessary for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. § 1395y(a)(1)(A).

63. Pursuant to 42 C.F.R. § 414.36, payment for drugs, such as imaging contrast agents, incident to a physician's service under Medicare Part B are made in accordance 42 C.F.R. § 405.517.

64. Medicare Part B covers diagnostic imaging contrast agents, and covered Bracco's agents at issue in this matter for all relevant times.

65. Before participating in Government funded healthcare programs, Defendants and other such providers are required to certify compliance with Medicare's rules and regulations, including but not limited to, the AKS. Thereafter, each time Defendants or any other such provider submits a claim for payment, it is required to recertify its continued compliance.

66. When enrolling with Medicare, a provider must sign an initial enrollment application and periodically submit new applications as part of the revalidation process. Certification Statement, Sec. 5, CMS Form 855, Medicare Enrollment Application, Institutional Providers, *available at* https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms855a.pdf. As part of its agreement with Medicare, a provider certifies the following:

> I have read and understand the Penalties for Falsifying Information, as printed in this application. I understand that any deliberate omission, misrepresentation, or falsification of any information contained in this application or contained in any communication supplying information to Medicare, or any deliberate alteration of any text on this application, may be punishable by criminal, civil, or administrative penalties including, but not limited to, the denial or revocation of Medicare billing privileges, and/or the imposition of fines, civil damages, and/or imprisonment.
>
> * * *
>
> I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions . . . , and on the provider's compliance with all applicable conditions of participation in Medicare.
>
> * * *
>
> I will not knowingly present or cause to be presented a false or fraudulent claim for payment by Medicare, and I will not submit claims with deliberate ignorance or reckless disregard of their truth or falsity.

Id.

67. After its initial certification, a provider has an ongoing duty to notify Medicare if

anything on the form becomes untrue or inaccurate:

> If I become aware that any information in this application is not true, correct, or complete, I agree to notify the Medicare fee-for-service contractor of this fact in accordance with the time frames established in 42 C.F.R. § 424.516(e).
>
> * * *
>
> I agree to notify the Medicare contractor of any future changes to the information contained in this application in accordance with the time frames established in 42 C.F.R. § 424.516(e).

Id.

68. In addition to the initial and ongoing certifications, each time a provider submits a claim, electronically or otherwise, the submission must state, in boldface type, immediately preceding the claimant's signature:

> **"This is to certify that the foregoing information is true, accurate, and complete."**
>
> **"I understand that payment of this claim will be from Federal and State funds, and that any falsification, or concealment of a material fact, may be prosecuted under Federal and State laws."**

42 C.F.R. § 455.18(a) (emphasis added). Medicare Claims Processing Manual, Ch. 24 § 30.2 A, *available at* https://www.cms.gov/Regulations-andGuidance/Guidance/Manuals/downloads/clm104c24.pdf.

69. For each individual claim for payment, Defendants and other such healthcare providers must submit a CMS Form 1450, which reflects the name of the patient, the type of service provided, the total charges, and the date of the service. CMS Form 1450 requires the provider to certify its understanding "that misrepresentation or falsification of essential information . . . requested by [the form] may serve as the basis for civil monetary penalties and assessments and may upon conviction include fines and/or imprisonment under federal and/or state law(s)" and that the provider "did not knowingly or recklessly disregard or misrepresent or conceal

material facts." UB-04 Uniform Bill, CMS Form 1450 (03/01/2007), *available at* https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R1104CP.pdf.

iii. CHAMPUS/TRICARE, CHAMPVA, and FEHBP

70. In addition to Medicaid, Medicare Part A, Part B, and the federal and state governments reimburse a portion of the cost of contrast media agents and related services under several other federal and state health care programs, including but not limited to CHAMPUS/TRICARE, CHAMPVA, and Federal Employees Health Benefit Program ("FEHBP").

71. The Civilian Health and Medical Program of the Uniformed Services ("CHAMPUS") and TRICARE, a continuation of CHAMPUS, are federally funded uniformed services health care programs for active duty and retired service members, members of the National Guard and Reserve, service members' families, survivors of service members, and certain former spouses of service members. The Civilian Health and Medical Program of the Department of Veterans Affairs ("CHAMPVA"), is a federally funded healthcare program for the families and survivors of veterans who have been rated permanently and totally disabled for a service-connected disability and for the survivors of a military member who died in the line of duty, not due to misconduct. FEHBP is administered by the Office of Personnel Management and provides health insurance for federal employees, retirees, and survivors. Coverage of prescription drugs under these programs is similar to coverage under the Medicaid program. *See, e.g.*, 32 C.F.R. §§ 199.2 and 199.4(g)(15)(i); TRICARE Policy Manual 6010.54-M, Chapter 8, Section 9.1(8)(2) (August 2002); CHAMPVA Policy Manual, Chapter 2, Section 22.1, Art. II.

C. Prohibition of Kickbacks Associated with Medicaid, Medicare, CHAMPUS/TRICARE, CHAMPVA, and FEHBP

i. Federal Anti-Kickback Statute

72. The Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), makes it illegal for an individual knowingly and willfully to offer or pay remuneration in cash or in kind to induce a physician to order a good or service that is reimbursed by a federal healthcare program. *See* 42 U.S.C. § 1320a-7b(b)(2). "Remuneration" is broadly defined to include anything of value offered or paid in return for purchasing, ordering, or recommending the purchase or order of any item reimbursable by a federal healthcare program. *See* Department of Health and Human Services, Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731, 23734, 23737 (May 5, 2003).

73. The purpose of the Anti-Kickback Statute is to prohibit such remuneration in order to secure proper medical treatment and referrals and to limit unnecessary treatment, services, or goods that are based not on the needs of the patient but on improper incentives given to others, thereby limiting the patient's right to choose proper medical care and services. *See* Medicare and Medicaid Programs; Fraud and Abuse OIG Anti-Kickback Provisions, 54 Fed. Reg. 3088, 3089 (proposed Jan. 23, 1989) (to be codified 42 C.F.R. pt. 1001) ("[I]t is necessary for the fiscal integrity of the Medicare and Medicaid programs to assure that physicians exercise sound, objective medical judgment when controlling admittance [of new drugs and medical devices] to ... the medical marketplace.").

74. In accordance with the Anti-Kickback Statute, Medicare and Medicaid regulations directly prohibit any provider from receiving remuneration paid with the intent to induce referrals that takes into account the "volume or value" of any referrals or business generated. *See* 42 C.F.R. § 1001.952(f)(2). Such remuneration amounts to a kickback and can increase the

expenditures paid by Government funded health benefit programs by leading to over-utilization of prescription drugs and/or inducing medically unnecessary and excessive reimbursements. Kickbacks also effectively reduce patients' healthcare choices, because unscrupulous (or unknowing) physicians steer their patients to various products based on the physician's own interests rather than the patients' medical needs.

75. The Medicare and Medicaid Patient and Program Protection Act of 1987 authorizes the exclusion of an individual or entity from participation in the Medicare and Medicaid programs if it is determined that the party has violated the Anti-Kickback Statute. In addition, the Balanced Budget Act of 1997 amended that Act to impose an administrative civil monetary penalty for Anti-Kickback Statute violations: $50,000 for each act and an assessment of not more than three times the amount of remuneration offered, paid, solicited or received, without regard to whether a portion of such remuneration was offered, paid, solicited or received for a lawful purpose. *See* 42 U.S.C. § 1320a-7a(a)(7).

76. Paying kickbacks taints an entire prescription, regardless of the medical propriety of its use. The kickback inherently interferes with the doctor-patient relationship and creates a conflict of interest, potentially putting the patient's health at risk. Any defendant convicted under the statute is automatically barred from participating in federal and federally-funded healthcare programs.

ii. OIG, PhRMA, AMA and ACCME's Guidelines on the Manufacturer- Doctor Relationship and Behaviors that Violate the Anti-Kickback Statute

77. Recognizing that the Anti-Kickback Statute has been applied broadly, the OIG has acknowledged that liability under the statute will ultimately turn on intent. *See* Department of Health and Human Services, Office of Inspector General ("OIG") Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731 (May 5, 2003). In order to

assist pharmaceutical manufacturers, the OIG issued a guidance in May 2003 that not only stated its interpretation of the Anti-Kickback statute, but also highlighted activities that may give rise to liability under the statute. *See id*. The OIG Guidance also directed drug manufacturers to review the Pharmaceutical Research and Manufacturers of America ("PhRMA") Code, the Accreditation Council for Continuing Medical Education ("ACCME") standards relating to CMEs, and an ethical opinion issued in June 1992 and amended in April 2001 by the American Medical Association ("AMA") stating its guidelines to govern doctors' acceptance of gifts from pharmaceutical manufacturers. *See* AMA Opinion 8.061 (1992, amended 2001); PhRMA Code (2003); ACCME Standards (2004). All of these industry guidelines draw plain lines of demarcation for acceptable and unacceptable behavior under the Anti-Kickback statute.

78. The OIG's Guidance addressed specific practices commonly arising in the relationship between a drug manufacturer and physicians that present problems. *Id*. at 23738. Of particular concern to the OIG were "preceptorships," educational and research funding, CMEs, consulting and advisory arrangements, and gifts of more than trivial value to physicians such as entertainment, recreation, travel, and meals. *Id*. The OIG was also concerned about payments to physicians to: 1) listen to sales representatives market their drugs, 2) access marketing web sites, or 3) perform "research" for drug manufacturers. *Id*.

79. The AMA, PhRMA and ACCME guidelines have suggested similar limits on pharmaceutical activities. Where the three guidelines share the same perspectives on improper

activities, one can presume these activities are likely to violate the federal Anti-Kickback statute.[2]

80. The issuance of these guidelines by the OIG, AMA, PhRMA and ACCME, in addition to the enactment of the Anti-Kickback Statute itself, demonstrates that federal and state health care programs consider compliance with the Anti-Kickback Statute a prerequisite to receiving or retaining reimbursement payments from Medicaid, Medicare Part A, Medicare Part B and other federal health care programs.

81. AMA policy states that "[t]o avoid the acceptance of inappropriate gifts, physicians should observe the following guidelines:

> (1) Any gifts accepted by physicians individually should primarily entail a benefit to patients and should not be of substantial value. . . . Cash payments should not be accepted.
>
> (2) Individual gifts of minimal value are permissible as long as the gifts are related to the physician's work (e.g., pens and notepads).
>
> * * *
>
> (7) No gifts should be accepted if there are strings attached. For example, physicians should not accept gifts if they are given in relation to the physician's prescribing practices. In addition, when companies underwrite medical conferences or lectures other than their own, responsibility for and control over the selection of content, faculty, educational methods, and materials should belong to the organizers of the conferences or lectures.

American Medical Association, Council on Ethical and Judicial Affairs, "Gifts to Physicians from Industry," AMA Ethical Opinion 8.061.

82. AMA policy also prohibits physicians from accepting "any kind of payment or compensation from a drug company . . . for prescribing its products." *See* AMA Ethical Opinions 6.04 (Fee Splitting); *see also* AMA Ethical Opinion 6.02 (Fee Splitting).

[2] The three guidelines all address several pharmaceutical activities, such as gifts, entertainment, conferences, CMEs, and consultants. The ACCME standards address only CME activities.

83. The American College of Physicians' Ethics Manual ("Ethics Manual") recognizes "drug industry gifts" as having potentially negative influence on clinical judgment and notes that it is "unethical for a physician to receive a commission or a kickback from anyone, including a company that manufactures or sells . . . medications that are used in the care of the physician's patients." *See* Ethics Manual, Financial Conflicts of Interest. Free or discounted equipment or services to physicians are "suspect" under the CMPL, 42 U.S.C. § 1320a; Office of Inspector General Guidance, COMPLIANCE PROGRAM GUIDANCE FOR PHARMACEUTICAL MANUFACTURERS, 68 Fed. Reg. 86 at 23731.

84. Free or discounted equipment or services, such as power injectors or business management consulting services to physicians are "suspect" under the Anti-Kickback Statute, 42 U.S.C. §1320(a), *et seq.*, as are educational grants and payments to physicians for consulting services. *See* Office of Inspector General Guidance, Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 86 at 23731.

85. Any remuneration that originates through the sales and marketing functions—or that are offered to doctors in connection with sales contacts—are particularly suspect under the Anti-Kickback Statute. *See* OIG Guidance, 68 Fed. Reg. at 23735. Most dubious in this regard are free goods that are initiated or directed by the sales or marketing agents: "if goods or services provided by the manufacturer eliminate an expense that the physician would have otherwise incurred (i.e., have independent value to the physician), or if items or services are sold to a physician at less than their fair market value, the arrangement may be problematic if the arrangement is tied directly or indirectly to the generation of federal health care program business for the manufacturer. Moreover, under the anti-kickback statute, neither a legitimate purpose for an arrangement (e.g., physician education), nor a fair market value payment, will necessarily

protect remuneration if there is also an illegal purpose (i.e., the purposeful inducement of business)." *Id*. at 23737.

VI. BRACCO'S SCHEME TO SELL CONTRAST MEDIA AGENTS THROUGH ILLEGAL KICKBACKS.

A. Relator's Background & Summary

86. Relator is currently employed by Philips Health Systems North America as an imaging account manager serving the New York metro area. Previously he worked for Bayer's Radiology/Interventional Division, in Wayne, New Jersey since May 2005. During his career at Bayer, Relator was an Executive Sales Consultant responsible for sales of software and imaging injectors to hospitals, radiologists, cardiologists, neurologists, vascular surgeons, nuclear medicine specialists and physicists.

87. During his career at Bayer, Relator discovered that Bracco was offering free power injectors to induce sales of its contrast media agents.

88. Bayer lost existing accounts, that Relator managed, and potential accounts as a result of Bracco's kickback scheme.

B. Contrast Media Products and Radiology Overview

i. Diagnostic Imaging

89. Diagnostic imaging lets doctors look inside [the] body for clues about a medical condition. A variety of machines and techniques can create pictures of the structures and activities inside [the] body. The type of imaging [a] doctor uses depends on [the] symptoms and the part of [the] body being examined.

90. CT scan and CT colonography combines a series of X-ray images taken from different angles around the body and uses computer processing to create cross-sectional images (slices) of the bones, blood vessels and soft tissues inside the body. CT scan images provide more-

detailed information than plain X-rays do. A CT scan has many uses, but it's particularly well-suited to quickly examine people who may have internal injuries from car accidents or other types of trauma. A CT scan can be used to visualize nearly all parts of the body and is used to diagnose disease or injury as well as to plan medical, surgical or radiation treatment.

91. MRI uses a magnetic field and radio waves to create clear and detailed cross-sectional images of your head and body.

92. Nuclear medicine is a medical specialty which uses radioactive tracers (radiopharmaceuticals) to diagnose and treat disease. Specially designed cameras allow doctors to track the circulation, uptake and excretion of these radioactive tracers. Single Photon Emission Computed Tomography ("SPECT") and Positron Emission Tomography ("PET") are the two most common imaging technologies in nuclear medicine. The primary difference between SPECT and PET scans is the type of radiotracers used. While SPECT scans employ radiotracers that directly issue x-rays or gamma rays of lower energy, PET scans employ radiotracers that produce small particles called positrons, which then decay to produce higher energy gamma rays.

93. Cardiac Catheterization (Interventional Radiology) is a procedure used to diagnose and treat certain cardiovascular conditions. During cardiac catheterization, a long thin tube called a catheter is inserted in an artery or vein in the groin, neck or arm and threaded through the blood vessels to the heart. Using this catheter, doctors can then do diagnostic tests as part of a cardiac catheterization. Some heart disease treatments, such as coronary angioplasty and coronary stenting, also are done using cardiac catheterization.

94. Fluoroscopy is a study of moving body structures – similar to an X-ray movie. A continuous x-ray beam is passed through the body part being examined. The beam is transmitted

to a TV-like monitor so that the body part and its motion can be seen in detail. Fluoroscopy, as an imaging tool, enables physicians to look at many body systems, including the skeletal, digestive, urinary, respiratory, and reproductive systems. Fluoroscopy may be performed to evaluate specific areas of the body, including the bones, muscles, and joints, as well as solid organs, such as the heart, lung, or kidneys.

95. Contrast Enhanced Ultrasound involves the administration of intravenous contrast agents consisting of microbubbles/nanobubbles of gas. Contrast-enhanced ultrasound has the advantage over contrast-enhanced MRI and CT in patients with contraindications such as renal failure or iodinated contrast allergy. CEUS also allows for dynamic and repeat examinations.

96. Myelography is an imaging examination that involves the introduction of a spinal needle into the spinal canal and the injection of contrast material in the space around the spinal cord and nerve roots (the subarachnoid space) using a real-time form of x-ray called fluoroscopy.

97. Bracco develops and markets products and devices for all of these diagnostic imaging modalities.

ii. Contrast Media Agents

98. Contrast Media Agents or Imaging Agents are substances injected into the body to enhance the blood and body tissues of patients for medical imaging, such as x-ray, CT scans, MRIs and ultrasound.

99. Imaging agents can be divided into four principal types: (1) barium-based media agents, (2) iodinated contrast media, (3) gadolinium-based media, and (4) microbubble-based contrast media.

100. The global contrast media market size is expected to reach $6 billion by 2024 from an estimate of $5 billion in 2019 . . . Growth in the market can primarily be attributed to the

increasing number of approvals of contrast agents, the rising volume of CT and MRI examinations globally, and the rapidly growing cancer and cardiovascular disease ("CVD") population across the globe. Rising research activities on contrast agents & their applications are the key areas of opportunity in this market. On the other hand, factors such as side-effects & allergic reactions, as well as the adverse effects associated with contrast agents are expected to limit market growth to a certain extent.

101. The iodinated contrast media segment is expected to command the largest share of the contrast media market in 2019. The high share of this segment can be attributed due to its high usage in CT examinations coupled with the fact that it can be used in almost all body parts. According to Relator, 2015 was the last year Bayer purchased any CT contrast market data; that year, within the CT contrast space, the market leader is GE, followed by Bracco; Bracco's CT contrast business was approximately 38% of the U.S. market; based on Relator's knowledge and experience, Bracco's market share has not dropped since 2015 but likely grown. Given the above, it is reasonable to estimate that Bracco generates at least $1 billion in annual revenue between all its contrast agents, disposables, and equipment business.

iii. Power Injectors

102. Power injectors, also known as pressure injectors, are used routinely in diagnostic and interventional radiology.

103. Pressure injectors or power injectors in imaging and interventional radiology ensure optimized opacification and delineation of normal anatomy, including arterial and venous anatomy and abnormal lesions. Today, several imaging and interventional studies require pressure injectors, as in CT (e.g., CT angiography, three-phase abdominal organ studies, cardiac CT, pre-

and post-stent analysis, and perfusion CT) and MRI (e.g., contrast-enhanced MR angiography, cardiac MRI, and perfusion MRI).

C. Bracco's Kickback Scheme

104. Bracco describes itself as a leader in innovative contrast imaging agents in the United States. It manufactures products for all key diagnostic imaging modalities including: CT scan and CT colonography; MRI; Nuclear medicine and radiopharmaceuticals; Cardiac Catheterization and Interventional Radiology; Fluoroscopy; CEUS; and Myelography.

105. Contrast Media Products and the Power Injector equipment used to administer these contrast agents are the heart of Bracco's business.

106. Bracco is one of the leading players in the contrast media market along with GE Healthcare (US-based), Bayer HealthCare (Germany-based), and Guerbet (France-based).

107. Prior to the amendment of the Sunshine Act, 42 U.S.C. § 1320a-7h, Covidian, a company no longer in the contrast/injector business, was one of the top three contrast media agents and power injector companies in the USA. It routinely provided free injector equipment with the sale of contrast products. For Covidian, free injection equipment was considered a cost of doing repeat business with medical facilities that required a steady supply of contrast agents to perform imaging services. Whereas competing companies such as, MEDRAD, later acquired by Bayer, formed alliances with other contrast vendors such as GE and even Bracco, to defend against Covidian's free injector placement program. These contrast media vendors would finance the cost of MEDRAD power injectors and pass the cost to their respective imaging or hospital customer base. When equipment is bundled as a part of the contrast media, it locks in its customers, making it difficult for the respective customers to shop for more competitive pricing in the open market. This is important to note, as the price of contrast keeps dropping, usually every 3 years. However,

after the Anti-Kickback Statute was amended, and policies shifted to strictly control and prohibit gifts to medical providers as incentives for medical supply sales, all companies in this industry ceased to supply free injector or equipment financed through contrast, except Bracco.

108. Defendant Bracco has engaged in a systematic practice to boost sales of its Contrast Media Products and Consumables illegally. Bracco's illegal activity includes paying kickbacks in the form of free Power Injectors to medical facilities that agree to purchase 90% of their Contrast Media Products and Consumables from Bracco. The free Power Injectors that Bracco supplies are large, sophisticated machines, installed in medical suites and valued at tens of thousands of dollars each, that can be used to inject or infuse imaging agents manufactured by any company, not just Bracco Contrast Media Products.

109. Bracco's scheme involves paying kickbacks to medical facilities in the form of free Power Injector equipment placement in exchange for their agreement to purchase and use a minimum quantity of Contrast Media Products and Consumables from Bracco which they use to service beneficiaries of, and submit false claims for payment to, Medicare, Medicaid and other Government Programs.

110. This scheme is perpetrated by entering into sham contracts with medical facilities for free Power Injector equipment to be delivered to and installed on-site at the facility; these "free" leases are contingent on the medical facilities making purchases of Contrast Media Products, Consumables, and accessories and training related applications (collectively, "Bracco Products").

111. Defendants furthered the scheme by concealing the kickback as a fictitious "lease" or a "discount" on the purchase of Bracco's Products; by avoiding transparency reporting required by the Sunshine Act, 42 U.S.C. § 1320a-7h; by misrepresenting the average sales price of the Contrast Media Products to Government agencies or by filing fraudulent cost reports with federal

agencies; and by causing to be filed, and filing, thousands of false claims for reimbursement for use of Bracco Products and the Power Injector in the provision of imaging related services to patients.

i. Bracco and Defendants Enter into Sham Lease Agreements to Disguise their Transactions.

112. According to documents obtained by the Relator, Bracco supplies facilities that purchase a minimum quantity of Bracco Products with free power injection equipment using their so-called Injector Placement Agreement (the "Kickback Agreement") prepared at Bracco's New Jersey office. With these fictitious agreements, for terms ranging from three to five years, Bracco purports to grant its customer "a nontransferable right to use" certain power injector equipment with Contrast Media Products purchased from Bracco.

113. According to the Kickback Agreement, the power injector equipment shall remain at the customer's location and under its "ownership or control."

114. The Kickback Agreement states that the power injector shall be used with Contrast Media Products and Consumables purchased from Bracco, even though the Agreement does not require a customer to purchase all imaging agents from Bracco and its power injectors work with media produced by other manufacturers.

115. The free power injector equipment is usually listed in a separate schedule to the Kickback Agreement. These power injectors work just as well with imaging agents produced by other manufacturers and the Kickback Agreement permits customers to purchase up to 10% of their imaging agents from other manufacturers.

116. The power injector Bracco supplies is a large, often ceiling mounted apparatus, costing tens of thousands of dollars; based on Relator's knowledge and information, Bracco will often supply more than one and sometimes as many as thirty power injectors to one customer.

117. Equipment sent to different facilities have been valued at $24,850 each. Schedules in sample "contracts" obtained by Relator, list the type, specifications and price of the equipment supplied free of charge.

118. A set of two free power injectors sent to another facility was valued at a total of $49,870; and Relator has information about Bracco replacing or supplying numerous free power injectors in proposals worth millions of dollars.

119. These free injectors are specifically conditioned on the purchase of a ***minimum quantity*** of Bracco Products, often described as "no less than ninety percent (90%)" of the customer's contrast media requirements.

120. Thus, a customer is still "free" to purchase up to ten percent (10%) of its imaging agents from other manufacturers and use them with Bracco's free injector.

121. Through this scheme, Bracco is knowingly paying tens of thousands of dollars in kickbacks, in the form of free power injection equipment, to medical facilities to induce them to purchase at least 90% of their annual contrast media agents over the course of several years.

122. Defendants may attempt to argue that ownership and title to the equipment never passes to the customer under their written agreements. But, as long as the customer continues to purchase its contrast media agents from Bracco, a customer will never pay for use of the equipment under the Kickback Agreement.

123. And, if a customer decides not to continue to purchase from Bracco at the end of the contract term, it can simply return the power injector regardless of how long it was used for free, or, purchase it at a 70% discount. Either way, a customer has received remuneration (a kickback, bribe or rebate) in return for purchasing Bracco's Products in violation of 42 U.S.C. § 1320a-7b(b).

ii. Defendants Conceal Their Scheme by Skirting Their Reporting Obligations.

124. To conceal their scheme, Defendants refer to these transactions as "leases" with a "waiver of royalties" for the use of the injector equipment, or, to the receipt of this equipment as "an additional discount on the sale" of Bracco's Products in the express language of the Kickback Agreement.

125. However, these "clever" efforts to disguise a kickback in written agreements that are clearly intended to provide free medical equipment in exchange for continuous purchases of contrast media agents and consumables and do not relieve Defendants of liability but rather evince their devious and purposeful intent to evade the Anti-Kickback Statute.

126. Moreover, these transactions do not meet the requirements of the "equipment leasing" and "discount" safe-harbors under the law. *See* 42 C.F.R. 1001.952 Exceptions.

127. According to 42 C.F.R. 1001.952(c), the "Equipment rental" exception to the Anti-Kickback statute, states that remuneration does not include any payment made by a lessee or equipment to the lessor for use of the equipment if the following pertinent conditions are met:

a. If the lease is intended to provide the lessee with use of the equipment for periodic intervals of time, ***rather than on a full-time basis*** for the term of the lease, the lease must specify exactly the schedule of such intervals, their precise length, and the exact rent for each interval; and

b. ***The aggregate rental charge is set in advance, is consistent with fair market value*** in arms-length transactions and is not determined in a manner that takes into account the volume or value of any referrals of business otherwise generated between the parties for which payment may be made in whole or in part under Medicare, Medicaid or all other Federal health care programs.

128. Defendants' written "Injector Placement Agreement" expressly violates these prerequisites of the "equipment rental" safe-harbor; Bracco provides its power injectors on a full-time basis (in fact they are often physically mounted at the customer's facility) and the injectors are provided for free – not at a fair market value rental charge.

129. According to 42 C.F.R. 1001.952(h)(5), the "Discount" exception to the Anti-Kickback Statute specifically excludes from the safe-harbor any discounts that may involve cash payments or "cash equivalents" or "supplying one good or service without charge or at a reduced charge to induce the purchase of a different good or service …." In this case, Defendants' scheme does not meet the definition of a "discount" required to shield them from liability because the Kickback Agreement explicitly conditions the free use of the power injector on large repeat purchases of Bracco Products.

130. Additionally, based on a review of publicly available information, and Relator's investigations, none of the Defendants are reporting the transfer or the receipt of the free injectors as payments or "transfers of value" as required by the Sunshine Act, 42 U.S.C. § 1320a-7h(a), further concealing their conspiracy.

131. Upon information and belief, Bracco is not taking these free power injectors into account in reporting its average sales prices of the Contrast Media Products to Government Agencies and none of the Provider Defendants are taking them into account when filing cost reports with federal agencies. On the contrary, Defendants are concealing these transactions from their reporting obligations are misrepresenting that they are in compliance with the AKS every time they seek reimbursement from the Government. Such claims for reimbursement are fraudulent and violate the FCA.

iii. Defendants File Tens of Thousands of False Claims and Misleading Reports.

132. All of the Provider Defendants – NYU Langone, DuPage, HonorHealth, Southern Illinois Health, and UNebraska – submit claims for reimbursement for the imaging services they provide to patients and the contrast media agents they use to perform those services.

133. Bracco is aware of the submission of such claims since these Provider Defendants, especially NYU Langone, publicly advertise treatment of Medicare and Medicaid beneficiaries, among patients who are covered by private insurance.

134. For Medicaid recipients, claims for radiology services and for contrast media agents are reimbursed through the private managed care plans or fee-for-service systems that vary by state.

135. For Medicare recipients, claims for radiology services and for contrast media agents are reimbursed through the Part A or Part B Program.

136. Inpatient radiology services are billed under Medicare Part A to fiscal intermediaries as well as A/B Medicare administrative coordinators and when patients receive outpatient radiology services, these services are paid under the Outpatient Prospective Payment System.

137. According to Medicare's Claims Processing Manual for Radiology Services and Other Diagnostic Procedures (Chapter 13) ("Medicare CPM"), depending on the service or diagnostic technique, claims for contrast material are either billed separately or bundled with the service procedure. *Compare* Medicare CPM Section 30.1.3 *with* Section 40. For example, for a MRI, a diagnostic procedure for brain and spinal MRIs on a single patient could involve three series of images: one MRI without contrast, a second MRI with contrast, and a third MRI with a double-dosage of contrast material. *See* Medicare CPM Section 40. Medicare sets out a

complex claims processing procedure for such instances, where contrast material is either billed separately or with the service and adjusted to avoid double-billing or account for additional contrast dosage. Bottom line, Defendants and/or their physicians are filing tens of thousands of claims for contrast media agents used in radiology services.

138. The FCA imposes liability not only on a person who presents a false or fraudulent claim, but also on a person who "causes" the false or fraudulent claim to be presented. 31 U.S.C § 3729(a)(1)(A). Additionally, it is well-settled that "the FCA reaches claims rendered false by one party, even if they are submitted to the Government by another downstream entity." *See United States ex rel. Wood v. Allergan, Inc.*, 246 F.Supp 3d 772, 819 (S.D.N.Y. 2017). "Where the defendant is a non-submitting entity, courts merely ask whether that entity knowingly caused the submission of either a false or fraudulent claim or false records or statements to get such a claim paid." *Id*. In this case, Defendants are liable for all of the claims for contrast material submitted by any physician at their facilities that falsely certified compliance with the Anti-Kickback Statute as a result of this scheme since 2010 when Congress amended the Anti-Kickback Statute to clarify that compliance with the AKS is a precondition to payment under Federal Government Programs. *See* 42 U.S.C. § 1320a-7b(g) ("a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of the [False Claims Act]"). The 2010 Amendment "made clear that compliance with the AKS is a precondition to the payment of claims submitted to these programs, and not merely a condition of participation in the programs." *See United States ex rel. Arnstein v. Teva Pharms, USA, Inc.*, 2016 U.S. Dist. LEXIS 22554 (S.D.N.Y. Feb. 22, 2016). "Accordingly, from and after March 2010, the act of submitting a claim for reimbursement itself implied compliance with the AKS [Anti-Kickback Statute]." *Id*. Defendants have conspired to violate the Anti-Kickback

Statute and are falsely certifying or causing their employees to falsely certify compliance with the AKS every time they file a claim for radiology services and contrast media reimbursements.

139. Bracco knows that these facilities will seek reimbursement for the contrast media agents they purchased and use of the free power injector equipment they received. Provider Defendants know that their Radiology departments and physicians will be submitting thousands of claims tainted by Bracco's power injector kickback scheme. Since reimbursement from the Government requires certification with the Anti-Kickback Statute, every claim Bracco caused Provider Defendants to submit, and every claim such Provider Defendants and their physicians actually submitted is rendered legally false. And it does not matter that said physicians may not have known about Bracco's conduct since Bracco induced the Provider Defendants to file kickback-tainted claims as a natural consequence of the scheme.

140. Moreover, since Provider Defendants are receiving a "discount" on the cost of the contrast media agents they purchased, Bracco may also be falsely reporting its Average Sales Prices ("ASPs") to various Government Health Programs. According to the U.S. Department of Health and Human Services, "[m]anufacturer reported ASPs serve as the basis for most Part B drug payment amounts" and manufacturers of contrast agents are among those submitting such reports.[3] If Bracco is not accounting for the value of the free power injector in its ASP reporting, it is also concealing its scheme with these false reports.

141. Finally, CMS requires the Provider Defendants to submit an annual cost report. Such costs reports constitute the final "claim" that a provider submits to the Medicare program for services rendered to Medicare beneficiaries. After the end of each hospital's fiscal year, the

[3] *See Limitations in Manufacturer Reporting of Average Sales Price Data for Part B Drugs*, HHS Office of Inspector General (July 2014) at p. available at https://oig.hhs.gov/oei/reports/oei-12-13-00040.pdf.

hospital files its cost report with its designated Medicare fiscal intermediary, stating the amount of reimbursement the provider believed it was due for the year. *See* 42 U.S.C. § 1395g(a); 42 C.F.R. § 413.20; *see also* 42 C.F.R. § 405.1801(b)(1). Medicare cost reports contain the following language:

> MISREPRESENTATION OR FALSIFICATION OF ANY INFORMATION CONTAINED IN THIS COST REPORT MAY BE PUNISHABLE BY CRIMINAL, CIVIL AND ADMINISTRATIVE ACTION, FINE AND/OR IMPRISONMENT UNDER FEDERAL LAW. FURTHERMORE, IF SERVICES IDENTIFIED IN THIS REPORT WERE PROVIDED OR PROCURED THROUGH THE PAYMENT DIRECTLY OR INDIRECTLY OF A KICKBACK OR WHERE OTHERWISE ILLEGAL, CRIMINAL, CIVIL AND ADMINISTRATIVE ACTION, FINES AND/OR IMPRISONMENT MAY RESULT.

See Form CMS 2552-10.

142. Furthermore, the person filing the report is required to certify on the face of the cost report that:

> to the best of my knowledge and belief, it [the hospital cost report] is a true, correct and complete statement prepared from the books and records of the provider in accordance with applicable instructions, except as noted. I further certify that I am familiar with the laws and regulations regarding the provision of health care services, and that the services identified in this cost report were provided in compliance with such laws and regulations.

See Form CMS 2552-10.

143. Medicare relies upon a hospital's cost report to determine whether the provider was entitled to more reimbursement than already received through interim payments or whether the provider was overpaid and was required to reimburse Medicare. *See* 42 C.F.R. §§ 405.1803, 413.60 and 413.64(f)(1). Upon information and belief, Provider Defendants are not accurately disclosing the cost of their radiology services by either failing to disclose the free contrast power injector equipment they are receiving from Bracco, or, accounting for its "discount" on the cost

of the contrast media agents reflected on their books, records and representations to CMS in these cost reports. Provider Defendants' misrepresentations in these cost reports would further conceal the kickback scheme and constitute additional false claims or misrepresentations in furtherance of their scheme to defraud the Government.

iv. Compensation for Off-Label Marketing

144. Finally, Bracco rewards its sales representatives in the form of bonuses based on the volume of sales they attain, regardless of whether the sales were ill-gotten with kickbacks.

VII. ACTIONABLE CONDUCT BY BRACCO UNDER THE FALSE CLAIMS ACT

A. Applicable Law

i. False Claims Act

145. This is an action to recover damages and civil penalties on behalf of the United States and Relator arising from the false or fraudulent statements, claims and acts by Bracco made in violation of the False Claims Act, 31 U.S.C. §§ 3729-3732.

146. The FCA provides that any person who:

a. knowingly presents, or causes to be presented a false or fraudulent claim for payment or approval;

b. knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;

c. conspires to defraud the Government by committing a violation of the FCA;

d. knowingly makes, uses, or causes to be made or used, a false record or statement to conceal material to an obligation to pay or transmit money or property to the Government

is liable to the Government for a civil penalty of not less than $11,665 and up to $23,331 for each such claim, plus three times the amount of damages sustained by the Government because of the false or fraudulent claim.

147. The FCA allows any persons having knowledge of a false or fraudulent claim against the Government to bring an action in federal district court for themselves and for the United States Government and to share in any recovery as authorized by 31 U.S.C. §3730.

148. Based on these provisions, Relator seeks through this action to recover damages and civil penalties arising from Defendants' causation of the submission of false claims to Federal and State Payors. In this case, such claims were submitted to the federal and state governments for payment for Bracco's contrast media agents. Relator alleges that the United States and the States have suffered significant damages as a result of false claims for payment for Bracco's contrast agents.

149. There are no bars to recovery under 31 U.S.C. §3730(e), and, or in the alternative, Relator is an original source as defined therein. Relator has direct and independent knowledge of the information on which the allegations are based. As required pursuant to 31 U.S.C. §3730(b) and (e), Relator has voluntarily provided information, oral and/or written, and has sent disclosure statement(s) of all material evidence, information and documents related to this Complaint, both before and contemporaneously with filing, to the Attorney General of the United States, the United States Attorney for the District of New Jersey, and the Attorneys General of the various states, commonwealths, and the District of Columbia.

ii. The Anti-Kickback Statute

150. The federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b) prohibits any person or entity from making or accepting payment to induce or reward any person for referring, recommending or arranging for federal-funded medical services, including services provided under Medicare and Medicaid programs.

151. In pertinent part, the AKS states:

> (b) Illegal remunerations
>
> (1) Whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—
>
> (A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program,
>
> (B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program, shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.
>
> (2) Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—
>
> (A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
>
> (B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program, shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

Violation of the AKS can also subject the perpetrator to exclusion from participation in federal health care programs and civil monetary penalties of $50,000 per violation and three times the amount of remuneration paid. 42 U.S.C. 1320a-7(b)(7) and (a)(7). The Patient Protection and Affordable Care Act ("PPACA"), Pub l. L No. 111-148, 124 Stat. 119 (2010), provides that violations of the AKS are per se violations of the FCA: "a claim that includes items or services

resulting from a violation of this section constitutes a false or fraudulent claim for the purposes of [the False Claims Act]."

152. The PPACA also clarified the intent requirement for the AKS and provides that "a person need not have actual knowledge of this section or specific intent to commit a violation" of the AKS in order to be found guilty of a "willful violation."

iii. The Sunshine Act

153. The Sunshine Act – also known as section 6002 of the Affordable Care Act ("ACA") of 2010 – requires medical product manufacturers to disclose to the CMS any payments or other transfers of value made to physicians or teaching hospitals. It also requires certain manufacturers and group purchasing organizations ("GPOs") to disclose any physician ownership or investment interests held in those companies.

B. Defendants' Violations of the FCA

i. Bracco's Kickback Scheme Violates the FCA

154. Because of the illegal acts described above, Bracco has made or will make millions of dollars from sales of Contrast Media Agents and Consumables and related services that will result in false claims being filed with Medicaid, Medicare, CHAMPUS/TRICARE, CHAMPVA, FEHBP, and other federal healthcare program.

155. Defendants violated the Anti-Kickback Statute by providing and accepting kickbacks in the form of free power injection equipment.

156. Defendants knew that kickbacks were intended to and in fact induced the purchase of Bracco Products and would ultimately lead to thousands of reimbursement claims tainted by kickbacks being submitted to the Government for payment. Defendants know the kickbacks render as fraudulent all claims submitted by their facilities, physicians and radiologists for reimbursement by the Government under these circumstances. Defendants continue to

submit such fraudulent claims for reimbursement; they continue to conceal the kickbacks from their Sunshine Act reporting obligations, from their Average Sale Price reports and from their annual cost reports to the Government.

157. Bracco's fraudulent scheme to pay illegal kickbacks led to increased and continued sales of Bracco Products. Reimbursement claims from Provider Defendants for radiology services, contrast media agents and consumables for which Medicaid, Medicare Part A, Medicare Part B, CHAMPUS/TRICARE, CHAMPVA, FEHBP, and other federal healthcare programs paid were a direct result of this illegal scheme. Thus, these Medicaid, Medicare Part A, Medicare Part B, CHAMPUS/TRICARE, CHAMPVA, FEHBP, and other Federal Healthcare Program claims for reimbursement are tainted by the associated illegal kickbacks. Bracco's scheme violated the Anti-Kickback Statute, and therefore caused false claims to be submitted by physicians in violation of the FCA. By orchestrating and taking part in this fraudulent scheme, Defendants repeatedly and with continued knowledge violated and continue to violate the False Claims Act, 31 U.S.C. § 3729(a).

158. Because of the illegal acts described above, Bracco has made or will make millions of dollars in sales of Contrast Media Agents and Consumables it would not otherwise achieve; and the Provider Defendants will earn hundreds of thousands of dollars in hidden "discounts" from free power injectors and rewards for tainted reimbursement claims. The ultimate submission by facilities, physicians and radiologists of false claims to the state Medicaid programs, Medicare, CHAMPUS/TRICARE, CHAMPVA, FEHBP, and other federal healthcare programs was a foreseeable factor in the Government's loss, and a consequence of the scheme. Given the structure of the health care systems, Defendants' false statements, representations, and records made, used, or caused to be made or used had the potential to influence the

Government's payment decision. Consequently, the States and the United States Government have suffered substantial damages.

ii. Bracco Conspired with the Provider Defendants to Defraud the Government in Violation of the FCA

159. Provider Defendants agreed to enter into the Kickback Agreement and purchase Bracco Products in exchange for free power injection equipment knowing such agreement was prohibited by the Anti-Kickback Statute and would result in violations of the FCA, the Sunshine Act and other reporting obligations.

160. Thus, Bracco conspired with the Provider Defendants to pay them kickbacks in order to induce them to purchase and use Bracco Products. As Bracco knew would be the case, Providers Defendants' actions resulted in the submission to state Medicaid programs, Medicare, CHAMPUS/TRICARE, CHAMPVA, FEHBP, and other federal healthcare programs of false and/or fraudulent claims for reimbursement, violating the FCA, 31 U.S.C. § 3729(a).

iii. Damages

161. Reimbursements for radiology services and contrast media agents that resulted from false certification would not have been reimbursed by Medicare Part A, Medicare Part B, the state Medicaid programs, CHAMPUS/TRICARE, CHAMPVA, FEHBP and other Federal Healthcare Programs, had the Government or the States known the circumstances under which the requests for reimbursement were submitted and the laws violated by Defendants in order to increase sales and obtain kickbacks to reduce operating costs. Consequently, the States and the Government have suffered substantial damages.

162. Relator does not know the full extent of Bracco's scheme; however, Bracco operates throughout the United States and internationally; the Provider Defendants named in this complaint are located throughout the country; upon information and belief, Bracco is supplying

free power injector kickbacks to Provider Defendants throughout the country, which potentially translates into millions of dollars of false claims and damages to the Government and the States.

VIII. CAUSES OF ACTION

Count 1
False Claims
31 U.S.C. § 3729(a)(1)(A)

163. Relator realleges and hereby incorporates by reference each and every allegation contained in the preceding paragraphs of this Complaint.

164. By virtue of the acts alleged herein, Defendants have knowingly presented or caused to be presented false or fraudulent claims for payment or approval in violation of 31 U.S.C. § 3729(a)(1)(A).

165. As a result of Bracco's kickback scheme and kickbacks to Defendant Providers to induce them to purchase Bracco's Contrast Media Agents and Consumables, all of the claims that Defendants caused physicians and third-party payers to submit to the state Medicaid programs, Medicare, CHAMPUS/TRICARE, CHAMPVA, FEHBP and other federal healthcare programs are false or fraudulent. Defendants knowingly caused such false or fraudulent claims to be presented for payment or approval, in violation of 31 U.S.C. § 3729(a)(l).

166. The United States Government paid the false and/or fraudulent claims.

167. By virtue of the false or fraudulent claims that Defendants knowingly caused to be presented, the United States Government has suffered substantial monetary damages.

168. As a result of Defendants' acts, the United States has been damaged, and continues to be damaged, in a substantial amount to be determined at trial, and the United States is entitled to penalties of at least $11,665 and up to $23,331 for each and every violation of 31 U.S.C. § 3729(a) arising from Defendants' unlawful conduct as described herein.

Count 2
Use of False Records or Statements
(31 U.S.C. § 3729(a)(1)(B))

169. Relator realleges and hereby incorporates by reference each and every allegation contained in the preceding paragraphs of this Complaint.

170. By virtue of the acts alleged herein, Defendants knowingly made, used, or caused to be made or used, false records or statements – *i.e.*, the false certifications and representations made or caused to be made by Defendants – material to false or fraudulent claims in violation of 31 U.S.C. § 3729(a)(1)(B).

171. Defendant's false claims or statements include, but are not limited to, false annual cost reports, false Average Sales Cost reporting, false Sunshine Act reports, and tainted claims for reimbursement submitted with false certification of compliance with the AKS.

172. By submitting claims for payment and retaining improperly obtained payments, Defendants expressly and impliedly, if falsely, certified to their compliance with the relevant Government and CMS regulations authorizing such payments.

173. Defendants knowingly made or used, or caused to be made or used, false records or statements, and omitted material facts (a) to get false or fraudulent claims paid or approved by the Government, or (b) that were material to false or fraudulent claims, in violation of 31 U.S.C. § 3729(a). The false records or statements included, but were not limited to, the false or misleading statements provided to the Government to induce the purchase of high volumes of Contrast Media Agents and Consumables, and the facilities' and physicians' and third-party payers' false certifications and representation of full compliance with all federal and state laws and regulations prohibiting fraudulent acts and false reporting, including but not limited to the Anti-Kickback Statute. By submitting claims for payment and retaining improperly obtained payments, Defendants expressly and impliedly, if falsely, certified their compliance with the

relevant Government and CMS regulations authorizing such payments. Each claim for reimbursement as a result of the Defendants' illegal inducements represents a false or fraudulent record or statement. And each claim for reimbursement submitted to a federal health insurance program represents a false and/or fraudulent claim for payment.

174. By virtue of the false records or statements that Bracco made or used, the United States Government has suffered substantial monetary damages.

175. As a result of Defendants' acts, the United States has been damaged, and continues to be damaged, in a substantial amount to be determined at trial, and the United States is entitled to at least $11,665 and up to $23,331 for each and every violation of 31 U.S.C. § 3729 arising from Defendants' unlawful conduct as described herein.

Count 3
False Claims Conspiracy
(31 U.S.C. § 3729(a)(1)(C))

176. Relator realleges and hereby incorporates by reference each and every allegation contained in the preceding paragraphs of this Complaint.

177. Defendants conspired to further the sale and purchase of Contrast Media Agents and Consumables with false claims and statements in violation of the FCA and to pay and accept kickbacks in violation of the Anti-Kickback Statute to induce multi-year contracts for high volumes of Bracco Products, thereby causing all of the facilities', physicians' and third-party payers' claims to the state Medicaid programs, Medicare, CHAMPUS/TRICARE, CHAMPVA, FEHBP, and other Federal Healthcare Programs to be false or fraudulent.

178. Accordingly, Bracco and the Provider Defendants conspired to defraud the Government by (a) getting false or fraudulent claims allowed or paid, and/or (b) committing a violation of the FCA, in violation of 31 U.S.C. § 3729(a), and/or (c) by concealing the receipt of free injectors from Sunshine reporting, annual cost reporting and Average Sales Price reporting.

By virtue of the false or fraudulent claims submitted, paid, or approved as a result of Defendants' conspiracy to defraud the Government, the United States has suffered substantial monetary damages.

Count 4
Reverse False Claims
31 U.S.C. § 3729(a)(1)(G))

179. Relator realleges and hereby incorporates by reference each and every allegation contained in the preceding paragraphs of this Complaint.

180. By virtue of the acts alleged herein, Defendants knowingly made, used, or caused to be made or used, false records or false statements that are material to an obligation to pay, transmit, or return money to the Government.

181. As a result of Defendants' acts, the United States has been damaged, and continues to be damaged, in a substantial amount to be determined at trial, and the United States is entitled to at least $11,665 and up to $23,331 for each and every violation of 31 U.S.C. §3729(a)(1)(G) arising from Defendants' unlawful conduct as described herein.

Count 5
Violations of the Anti-Kickback Statute
(42 U.S.C. § 1320a-7b, *et seq.*)

182. Relator realleges and hereby incorporates by reference each and every allegation contained in the preceding paragraphs of this Complaint.

183. As more particularly set forth in the foregoing paragraphs, Bracco offered and/or Defendants and their professional employees solicited and accepted kickbacks from Bracco. These kickbacks took the form of free power injector equipment, sophisticated machines valued at tens of thousands of dollars each, to be used with Contrast Media Agents and Consumables purchased from Bracco and other manufacturers, in exchange for multi-year contracts to purchase large volumes of these Bracco Products.

184. As a result of these unlawful kickbacks, Relator has direct knowledge of Provider Defendants electing to purchase Bracco Products despite the existence of other, less expensive, viable alternatives.

185. This behavior caused the Government to pay more for services rendered than was medically necessary, in violation of the Anti-Kickback Statute.

186. The Anti-Kickback Statute contains statutory exceptions and regulatory "safe harbors" excluding certain types of conduct from liability. *See* 42 U.S.C. § 1320a-7(b)(3) and 42 C.F.R. § 1001.952. None of these statutory exceptions or regulatory safe harbors apply in this matter.

Count 6
California False Claims Act
(Cal. Gov't Code § 12650, *et seq.*)

187. Relator repeats and realleges each allegation contained in the preceding paragraphs of this Complaint.

188. This is a *qui tam* action brought by Relator and the State of California to recover treble damages and civil penalties under the California False Claims Act, Cal. Gov't. Code § l2650, *et seq*.

189. Cal. Gov't Code§ 12651(a) provides liability for any person who-

(a) knowingly presents, or causes to be presented, to an officer or employee of the state or of any political division thereof, a false claim for payment or approval;

(b) knowingly makes, uses, or causes to be made or used a false record or statement to get a false claim paid or approved by the state or by any political subdivision;

(c) conspires to defraud the state or any political subdivision by getting a false claim allowed or paid by the state or by any political subdivision;

(d) knowingly makes, uses, or causes to made or used a false

> record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the state or to any political subdivision;
>
> (e) is a beneficiary of an inadvertent submission of a false claim to the state or a political subdivision, subsequently discovers the falsity of the claim, and fails to disclose the false claim to the state or the political subdivision within a reasonable time after discovery of the false claim.

190. In addition, the payment or receipt of bribes or kickbacks is prohibited under Cal. Bus. & Prof. Code §§ 650 and 650.1, and is also specifically prohibited in treatment of Medi-Cal patients pursuant to Cal. Welf. & Inst. Code §14107.2.

191. Defendants knowingly violated Cal. Gov't Code § 12651(a) and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of California from at least January 2010 to the present by violating Cal. Bus. & Prof. Code§§ 650-650.1 and Cal. Welf, & Inst. Code §14107.2 and the Federal Anti-Kickback Act, as described herein.

192. As a result of Bracco's kickback scheme all of the claims that Provider Defendants knowingly caused their facilities, physicians and radiologists to knowingly submit to the California Medicaid program are false or fraudulent. Further, Defendants knowingly caused facilities, physicians and radiologists to falsely certify, expressly and/or impliedly, and represent full compliance with all federal and state laws and regulations prohibiting fraudulent acts and false reporting, including but not limited to the Anti-Kickback Statute and the California Anti-Kickback Statutes (Cal. Bus. & Prof. Code§§ 650-650.1 and Cal. Welf. & Inst. Code §14107.2). Compliance with federal and state laws and regulations was a condition of payment.

193. The State of California, by and through the California Medicaid program and other state health care programs, paid the false and/or fraudulent claims.

194. Given the structure of the health care systems, the false statements, representations, and records made by Defendants had the potential to influence the State of California's payment decision.

195. The ultimate submission by facilities, physicians, and third-party payers of false and/or fraudulent claims to the state Medicaid program was a foreseeable factor in the State of California's loss, and a consequence of the scheme.

196. As a result of Defendants' violations of Cal. Gov't Code §12651(a), the State of California has been damaged.

197. There are no bars to recovery under Cal. Gov't Code § 12652(d)(3), and, or in the alternative, Relator is an original source as defined therein. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Cal. Gov't Code § 12652(c) on behalf of himself and the State of California.

198. This Court is requested to accept pendent jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the State of California in the operation of its Medicaid and other health programs.

Count 7
California Insurance Fraud Prevention Act
(Cal Ins. Code §§ 1871.1, *et seq.*)

199. Relator repeats and realleges each allegation contained in the preceding paragraphs of this Complaint

200. This is a claim for treble damages and penalties under the CIFPA.

201. Pursuant to Cal. Ins. Code § 1871.4(a), it is unlawful to:

> (1) Make or cause to be made a knowingly false or fraudulent material statement or material representation for the purpose of obtaining or denying any compensation, as defined in Section 3207 of the Labor Code.

> (2) Present or cause to be presented a knowingly false or fraudulent written or oral material statement in support of, or in opposition to, a claim for compensation for the purpose of obtaining or denying any compensation, as defined in Section 3207 of the Labor Code.
>
> (3) Knowingly assist, abet, conspire with, or solicit a person in an unlawful act under this section.
>
> (4) Make or cause to be made a knowingly false or fraudulent statement with regard to entitlement to benefits with the intent to discourage an injured worker from claiming benefits or pursuing a claim. For the purposes of this subdivision, "statement" includes, but is not limited to, a notice, proof of injury, bill for services, payment for services, hospital or doctor records, X–ray, test results, medical–legal expense as defined in Section 4620 of the Labor Code, other evidence of loss, injury, or expense, or payment.
>
> (5) Make or cause to be made a knowingly false or fraudulent material statement or material representation for the purpose of obtaining or denying any of the benefits or reimbursement provided in the Return–to–Work Program established under Section 139.48 of the Labor Code.
>
> (6) Make or cause to be made a knowingly false or fraudulent material statement or material representation for the purpose of discouraging an employer from claiming any of the benefits or reimbursement provided in the Return–to–Work Program established under Section 139.48 of the Labor Code.

202. By virtue of the acts described above, Defendants knowingly utilized a scheme by which they presented, or caused to be presented, false or fraudulent claims to private insurers in California, or for patients in California that those insurers covered (i.e., patients who hold private insurance contracts and against whom Defendants could file claims for payment or approval) in violation of each patient's private health insurance contract.

203. By virtue of the acts described above, Defendants knowingly made, used or caused to be made or used false records and statements and omitted material facts to induce the private insurers in California, or for patients in California covered by those insurers, to approve or pay such false and fraudulent claims.

204. By virtue of the acts described above, Defendants conspired to violate the CIFPA and each patient's private health insurance contract.

205. The private insurers in California, or those insurers that covered patients in California, unaware of the falsity of the records, statements and claims made, used, presented or caused to be presented by Defendants, paid and continue to pay the claims that are non-payable as a result of Defendants' illegal conduct.

206. Defendants knowingly submitted and/or caused to be made or used false records or false statements in order to avoid or decrease its obligation to return overpayments to these private insurance companies.

207. By reason of Defendants' acts, these private insurance companies have been damaged, and continue to be damaged, in a substantial amount to be determined at trial.

208. Each claim for reimbursement that was a result of Defendants' scheme represents a false or fraudulent record or statement and a false or fraudulent claim for payment.

209. The State of California is entitled to the maximum penalty of $150,000 per violation, plus an assessment of three times the amount of each false or fraudulent claim for compensation made, used, presented or caused to be made, used, or presented by Defendants.

Count 8
Colorado Medicaid False Claims Act
(C.R.S.A. § 25.5-4-304, *et seq*.)

210. Relator repeats and realleges each allegation contained in the preceding paragraphs of this Complaint.

211. This is a *qui tam* action brought by Relator on behalf of the State of Colorado to recover treble damages and civil penalties under the Colorado Medicaid False Claims Act, C.R.S.A. § 25.5-4-304, *et seq*.

212. Colorado's Medicaid False Claims Act, C.R.S.A. § 25.5-4-305, provides for liability for any person who

(a) Knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;

(b) Knowingly makes, uses, or causes to be made or used a false record or statement material to a false or fraudulent claim;

(c) Has possession, custody, or control of property or money used, or to be used, by the state in connection with the "Colorado Medical Assistance Act" and knowingly delivers, or causes to be delivered, less than all of the money or property;

(d) Authorizes the making or delivery of a document certifying receipt of property used, or to be used, by the state in connection with the "Colorado Medical Assistance Act" and, intending to defraud the state, makes or delivers the receipt without completely knowing that the information on the receipt is true;

(e) Knowingly buys, or receives as a pledge of an obligation or debt, public property from an officer or employee of the state in connection with the "Colorado Medical Assistance Act" who lawfully may not sell or pledge the property;

(f) Knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the state in connection with the "Colorado Medical Assistance Act", or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the state in connection with the "Colorado Medical Assistance Act";

(g) Conspires to commit a violation of paragraphs (a) to (f) of this subsection (1).

213. Defendants violated the Colorado Medicaid False Claims Act and knowingly caused false claims to be made, used and presented to the State of Colorado by its deliberate and systematic violation of federal and state laws and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

214. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was a condition of payment of claims submitted to the State of Colorado

in connection with Defendants' conduct. Compliance with applicable Colorado statutes was also a condition of payment of claims submitted to the State of Colorado.

215. Had the State of Colorado known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

216. As a result of Defendants' violations of the Colorado Medicaid False Claims Act, the State of Colorado has been damaged in an amount far in excess of millions of dollars exclusive of interest.

217. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to the Colorado Medicaid False Claims Act on behalf of himself and the State of Colorado.

218. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Colorado in the operation of its Medicaid program

Count 9
Connecticut False Claims Act
(Conn. Gen. Stat. § 4-274, *et seq*. (2014))

219. Relator repeats and realleges each allegation contained in the preceding paragraphs of this Complaint.

220. This is a *qui tam* action brought by Relator on behalf of the State of Connecticut to recover treble damages and civil penalties under the Connecticut False Claims Act, Conn. Gen. Stat. § 17b-301a, *et seq*.

221. Conn. Gen. Stat. § 4-275 imposes liability as follows:

(a) No person shall:

(1) Knowingly present, or cause to be presented, a false or fraudulent claim for payment or approval under a state-administered health or human services program;

(2) Knowingly make, use or cause to be made or used, a false record or statement material to a false or fraudulent claim under a state-administered health or human services program;

(3) Conspire to commit a violation of this section;

(4) Having possession, custody or control of property or money used, or to be used, by the state relative to a state-administered health or human services program, knowingly deliver, or cause to be delivered, less property than the amount for which the person receives a certificate or receipt;

(5) Being authorized to make or deliver a document certifying receipt of property used, or to be used, by the state relative to a state-administered health or human services program and intending to defraud the state, make or deliver such document without completely knowing that the information on the document is true;

(6) Knowingly buy, or receive as a pledge of an obligation or debt, public property from an officer or employee of the state relative to a state-administered health or human services program, who lawfully may not sell or pledge the property;

(7) Knowingly make, use or cause to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the state under a state-administered health or human services program; or

(8) Knowingly conceal or knowingly and improperly avoid or decrease an obligation to pay or transmit money or property to the state under a state-administered health or human services program.

222. Defendants violated the Connecticut False Claims Act and knowingly caused false claims to be made, used and presented to the State of Connecticut by their deliberate and systematic violation of federal and state laws and by virtue of the fact that none of the claims

submitted in connection with their conduct were even eligible for reimbursement by the government-funded healthcare programs.

223. The State of Connecticut, by and through the Connecticut Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third-party payers in connection therewith.

224. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was a condition of payment of claims submitted to the State of Connecticut in connection with Defendants' conduct. Compliance with applicable Connecticut statutes was also a condition of payment of claims submitted to the State of Connecticut.

225. Had the State of Connecticut known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

226. As a result of Defendants' violations of the Connecticut False Claims Act, the State of Connecticut has been damaged in an amount far in excess of millions of dollars exclusive of interest.

227. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to the Connecticut False Claims Act on behalf of himself and the State of Connecticut.

228. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Connecticut in the operation of its Medicaid program.

Count 10
Delaware False Claims and Reporting Act
(6 Del. C. §1201, *et seq*.)

229. Relator repeats and realleges each allegation contained in the preceding paragraphs of this Complaint.

230. This is a *qui tam* action brought by Relator on behalf of the State of Delaware to recover treble damages and civil penalties under the Delaware False Claims and Reporting Act, 6 Del. C. Ann. tit. 6 § 1201, *et seq*.

231. 6 Del. C. § 1201(a) in pertinent part provides for liability for any person who:

> (1) Knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
>
> (2) Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
>
> (3) Conspires to commit a violation of paragraph (a)(1), (2), . . . or (7) of this section; or
>
> * * *
>
> (7) Knowingly makes, uses, or causes to be made or used a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government.

232. Defendants violated the Delaware False Claims and Reporting Act, 6 Del. C. Ann. tit. 6 § 1201 *et seq.*, and knowingly caused false claims to be made, used and presented to the State of Delaware by their deliberate and systematic violation of federal and state laws and by virtue of the fact that none of the claims submitted in connection with their conduct were even eligible for reimbursement by the government-funded healthcare programs.

233. The State of Delaware, by and through the Delaware Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

234. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and also an express condition of payment of claims submitted to the State of Delaware in connection with Defendants' conduct. Compliance with applicable Delaware statutes and regulations was also an express condition of payment of claims submitted to the State of Delaware.

235. Had the State of Delaware known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

236. As a result of Defendants' violations of the Delaware False Claims and Reporting Act, 6 Del. C. Ann. tit. 6 § 1201, *et seq.*, the State of Delaware has been damaged in an amount far in excess of millions of dollars exclusive of interest.

237. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to the Delaware False Claims and Reporting Act, 6 Del. C. Ann. tit. 6 § 1201, *et seq.*, on behalf of himself and the State of Delaware.

238. This Court is requested to accept pendent jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Delaware in the operation of its Medicaid program.

Count 11
Florida False Claims Act
(Fla, Stat. Ann. §68.081 and §68.082(2)(a)-(b))

239. Relator repeats and realleges each allegation contained in the preceding paragraphs of this Complaint.

240. This is a *qui tam* action brought by Relator on behalf of the State of Florida to recover treble damages and civil penalties under the Florida False Claims Act, Fla. Stat. § 68.081, *et seq*.

241. Fla. Stat. § 68.082(2) provides liability for any person who:

(a) Knowingly presents or causes to be presented a false or fraudulent claim for payment or approval;

(b) Knowingly makes, uses, or causes to be made or used a false record or statement material to a false or fraudulent claim; or

(c) Conspires to commit a violation of this subsection.

242. Defendants further violated Fla. Stat. § 68.082(2) and knowingly caused false claims to be made, used and presented to the State of Florida by engaging in the conduct alleged herein and by virtue of the fact that none of the claims submitted in connection with their conduct were even eligible for reimbursement by the government-funded healthcare programs.

243. The State of Florida, by and through the Florida Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

244. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was a condition of payment of claims submitted to the State of Florida in connection with Defendants' conduct. Compliance with applicable Florida statutes was also a condition of payment of claims submitted to the State of Florida.

245. Had the State of Florida known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

246. As a result of Defendants' violations of Fla. Stat. § 68.082(2), the State of Florida has been damaged in an amount far in excess of millions of dollars exclusive of interest.

247. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Fla. Stat. § 68.083(2) on behalf of himself and the State of Florida.

248. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Florida in the operation of its Medicaid program

Count 12
Georgia False Medical Claims Act
& Georgia Taxpayer Protection Against False Claims Act
Ga. Code Ann. 49-4-168, *et seq.* &
Ga. Code Ann. 23-3-120, et seq.

249. Relator repeats and realleges each allegation contained in the preceding paragraphs of this Complaint.

250. This is a *qui tam* action brought by Relator on behalf of the State of Georgia to recover treble damages and civil penalties under the Georgia False Medicaid Claims Act, Ga. Code Ann., § 49-4-168, *et seq*.

251. The Georgia False Medicaid Claims Act, Ga. Code Ann., § 49-4-168-1, imposes liability on any person who:

(1) Knowingly presents or causes to be presented to the Georgia Medicaid program

a false or fraudulent claim for payment or approval;

(2) Knowingly makes, uses, or causes to be made or used a false record or statement material to a false or fraudulent claim;

(3) Conspires to commit a violation of paragraph (1), (2), (4), (5), (6), or (7) of this subsection;

(4) Has possession, custody, or control of property or money used or to be used by the Georgia Medicaid program and knowingly delivers, or causes to be delivered, less than all of such property or money;

(5) Is authorized to make or deliver a document certifying receipt of property used, or to be used, by the Georgia Medicaid program and, intending to defraud the Georgia Medicaid program, makes or delivers the receipt without completely knowing that the information on the receipt is true;

(6) Knowingly buys, or receives as a pledge of an obligation or debt, public property from an officer or employee of the Georgia Medicaid program who lawfully may not sell or pledge the property; or

(7) Knowingly makes, uses, or causes to be made or used a false record or statement material to an obligation to pay or transmit property or money to the Georgia Medicaid program, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit property or money to the Georgia Medicaid program.

252. Defendants violated the Georgia False Medicaid Claims Act and knowingly caused false claims to be made, used and presented to the State of Georgia by their deliberate and systematic violation of federal and state laws and by virtue of the fact that none of the claims submitted in connection with their conduct were even eligible for reimbursement by the government-funded healthcare programs.

253. The State of Georgia, by and through the Georgia Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third-party payers in connection therewith.

254. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was a condition of payment of claims submitted to the State of Georgia in connection with Defendants' conduct. Compliance with applicable Georgia statutes was also a condition of payment of claims submitted to the State of Georgia.

255. Had the State of Georgia known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

256. As a result of Defendants' violations of the Georgia False Medicaid Claims Act, the State of Georgia has been damaged in an amount far in excess of millions of dollars exclusive of interest

257. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to the Georgia False Medicaid Claims Act on behalf of himself and the State of Georgia.

258. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Georgia in the operation of its Medicaid program.

Count 13
Hawaii False Claims Act
(Haw. Rev. Stat. § 661-21, *et seq.*)

259. Relator repeats and realleges each allegation contained in the preceding paragraphs of this Complaint.

260. This is a *qui tam* action brought by Relator on behalf of the State of Hawaii to recover treble damages and civil penalties under the Hawaii False Claims Act, Haw. Rev. Stat. § 661-21, *et seq*.

261. Section 661-21(a) provides liability for any person who:

> (1) Knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
>
> (2) Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
>
> * * *
>
> (6) Knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the State, or knowingly conceals, or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the State; or
>
> * * *
>
> (8) Conspires to commit any of the conduct described in this subsection.

262. Defendants violated Haw. Rev. Stat. § 661-21(a) and knowingly caused false claims to be made, used and presented to the State of Hawaii by the conduct alleged herein and by virtue of the fact that none of the claims submitted in connection with their conduct were even eligible for reimbursement by the government-funded healthcare programs.

263. The State of Hawaii, by and through the Hawaii Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

264. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was a condition of payment of claims submitted to the State of Hawaii in

connection with Defendants' conduct. Compliance with applicable Hawaii statutes was also a condition of payment of claims submitted to the State of Hawaii.

265. Had the State of Hawaii known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

266. As a result of Defendants' violations of Haw. Rev. Stat. § 661-21, the State of Hawaii has been damaged in an amount far in excess of millions of dollars exclusive of interest.

267. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Haw. Rev. Stat. § 661-21 on behalf of himself and the State of Hawaii.

268. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Hawaii in the operation of its Medicaid program.

Count 14
Illinois Whistleblower Reward and Protection Act
(740 ILCS 175, *et seq.*)

269. Relator repeats and realleges each allegation contained in the preceding paragraphs of this Complaint.

270. This is a *qui tam* action brought by Relator and the State of Illinois to recover treble damages and civil penalties under the Illinois Whistleblower Reward and Protection Act, 740 ILCS 175, *et seq*.

271. 740 ILCS l75/3(a) provides liability for any person who

(a) knowingly presents, or causes to be presented, to an officer or employee of the State of a member of the Guard a false or fraudulent claim for payment or approval;

(b) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State;

(c) conspires to defraud the State by getting a false or fraudulent claim allowed or paid;

(d) knowingly makes, uses, or causes to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the state or to any political subdivision.

272. In addition, 305 ILCS 5/8A-3(b) of the Illinois Public Aid Code (Vendor Fraud and Kickbacks) prohibits the solicitation or receipt of any remuneration, including any kickback, bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind in return for furnishing any item or service for which payment may be made in whole or in part under the Illinois Medicaid program.

273. Defendants knowingly violated 740 ILCS l75/3(a) and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Illinois from at least January 2010 to the present by violating the Illinois Anti-Kickback Statute 305 ILCS 5/8A-3(b) and the Federal Anti-Kickback Act, as described herein.

274. As a result of Defendants' off-label marketing and kickback schemes, all of the claims that Defendants knowingly caused facilities, physicians and radiologists to knowingly submit to the Illinois Medicaid program are false or fraudulent. Further, Defendants knowingly caused facilities, physicians and radiologists to falsely certify, expressly and/or impliedly, and represent full compliance with all federal and state laws and regulations prohibiting fraudulent acts and false reporting, including but not limited to the Anti-Kickback Statute and the Illinois Anti- Kickback Statute (305 ILCS 5/8A-3(b)). Compliance with federal and state laws and regulations was a condition of payment.

275. The State of Illinois, by and through the Illinois Medicaid program and other state health care programs, paid the false and/or fraudulent claims.

276. Given the structure of the health care systems, the false statements, representations, and records made by Defendants had the potential to influence the State of Illinois's payment decision.

277. The ultimate submission by facilities, physicians, radiologists, and third-party payers of false and/or fraudulent claims to the state Medicaid program was a foreseeable factor in the State of Illinois's loss, and a consequence of the scheme.

278. As a result of Defendants' violations of 740 ILCS 175/3(a), the State of Illinois has been damaged.

279. There are no bars to recovery under 740 ILCS 175/4(e)(4), and, or in the alternative, Relator is an original source as defined therein. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to 740 ILCS 175/4(b) on behalf of himself and the State of Illinois.

280. This Court is requested to accept pendent jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Illinois in the operation of its Medicaid program.

Count 15
Illinois Insurance Claims Fraud Prevention Act
740 Ill. Comp. Stat. § 92/1, *et seq*.)

281. Relator repeats and realleges each allegation contained in the preceding paragraphs of this Complaint.

282. This is a claim for treble damages and penalties under the Illinois Insurance Claims Fraud Prevention Act ("IICFPA").

283. Pursuant to 740 Ill. Comp. Stat. § 92/5(a):

> A person who violates any provision of this Act, . . . or Section 17-10.5 of the Criminal Code . . . shall be subject, in addition to any other penalties that may be prescribed by law, to a civil penalty of not less than $5,000 nor more than $10,000, plus an assessment of not more than 3 times the amount of each claim for compensation under a contract of insurance.

284. 740 Ill. Comp. Stat. § 5/17-10.5 provides, in pertinent part:

> (a) Insurance fraud.
>
> > (1) A person commits insurance fraud when he or she knowingly obtains, attempts to obtain, or causes to be obtained, by deception, control over the property of an insurance company or self-insured entity by the making of a false claim or by causing a false claim to be made on any policy of insurance issued by an insurance company or by the making of a false claim or by causing a false claim to be made to a self-insured entity, intending to deprive an insurance company or self-insured entity permanently of the use and benefit of that property.
> >
> > (2) A person commits health care benefits fraud against a provider, other than a governmental unit or agency, when he or she knowingly obtains or attempts to obtain, by deception, health care benefits and that obtaining or attempt to obtain health care benefits does not involve control over property of the provider.
>
> * * *
>
> (c) Conspiracy to commit insurance fraud. . . .

285. By virtue of the acts described above, Defendants knowingly presented or caused to be presented false or fraudulent claims to the private insurers in Illinois, or for patients in Illinois that those insurers covered, for payment or approval in violation of each patient's private health insurance contract.

286. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements and omitted material facts to induce the private insurers in Illinois, or for patients in Illinois covered by those insurers, to approve or pay such false and fraudulent claims.

287. Defendants knowingly presented or caused to be presented false or fraudulent claims to the private insurers in Illinois, or for patients in Illinois those insurers covered, for payment or approval in violation of each patient's private health insurance contract.

288. By virtue of the acts described above, Defendants knowingly utilized a scheme by which it presented, or caused to be presented, false or fraudulent claims to private insurers in Illinois, or for patients in Illinois that those insurers covered (i.e., patients who hold private insurance contracts and against whom Defendants could file claims for payment or approval) in violation of each patient's private health insurance contract.

289. By virtue of the acts described above, Defendants conspired to violate the IICFPA and each patient's private health insurance contract.

290. The private insurers in Illinois, or those insurers that covered patients in Illinois, unaware of the falsity of the records, statements and claims made, used, presented, or caused to be presented by Defendants, paid and continue to pay the claims that are non-payable as a result of Defendants' illegal conduct.

291. Defendants knowingly submitted and/or caused to be made or used false records or false statements in order to avoid or decrease their obligations to return overpayments to these private insurance companies.

292. By reason of Defendants' acts, these private insurance companies have been damaged, and continue to be damaged, in a substantial amount to be determined at trial.

293. Each claim for reimbursement that was a result of Defendants' scheme represents a false or fraudulent record or statement and a false or fraudulent claim for payment.

294. State of Illinois is entitled to the maximum penalty of $10,000 per violation, plus an assessment of three times the amount of each false or fraudulent claim for compensation made, used, presented, or caused to be made, used, or presented by Defendants.

Count 16
Indiana False Claims and Whistleblower Protection Act
(Ind. Code § 5-11-5.5, *et seq.*)

295. Relator repeats and realleges each allegation contained in the preceding paragraphs of this Complaint.

296. This is a *qui tam* action brought by Relator on behalf of the State of Indiana to recover treble damages and civil penalties under the Indiana False Claims and Whistleblower Protection Act, Ind. Code 5-11-5.5-2, which imposes liability on:

> A person who knowingly or intentionally:
>
> (1) presents a false claim to the state for payment or approval;
>
> (2) makes or uses a false record or statement to obtain payment or approval of a false claim from the state;
>
> (3) with intent to defraud the state, delivers less money or property to the state than the amount recorded on the certificate or receipt the person receives from the state;
>
> (4) with intent to defraud the state, authorizes issuance of a receipt without knowing that the information on the receipt is true;
>
> (5) receives public property as a pledge of an obligation on a debt from an employee who is not lawfully authorized to sell or pledge the property;
>
> (6) makes or uses a false record or statement to avoid an obligation to pay or transmit property to the state;
>
> (7) conspires with another person to perform an act described in subdivisions (1) through (6); or
>
> (8) causes or induces another person to perform an act described in subdivisions (1) through (6) . . . .

297. Defendants violated the Indiana False Claims Act and knowingly caused false claims to be made, used and presented to the State of Indiana by their deliberate and systematic violation of federal and state laws and by virtue of the fact that none of the claims submitted in connection with their conduct were even eligible for reimbursement by the government-funded healthcare programs.

298. The State of Indiana, by and through the Indiana Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third-party payers in connection therewith.

299. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was a condition of payment of claims submitted to the State of Indiana in connection with Defendants' conduct. Compliance with applicable Indiana statutes was also a condition of payment of claims submitted to the State of Indiana.

300. Had the State of Indiana known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

301. As a result of Defendants' violations of Indiana's False Claims Act, the State of Indiana has been damaged in an amount far in excess of millions of dollars exclusive of interest.

302. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Ind. Code § 5-11-5.5, *et seq*. on behalf of himself and the State of Indiana.

303. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Indiana in the operation of its Medicaid program.

Count 17
Iowa False Claims Law
(I.C.A. § 685.1, *et seq*.)

304. Relator repeats and realleges each allegation contained in the preceding paragraphs of this Complaint.

305. This is a *qui tam* action brought by Relator on behalf of the State of Iowa to recover treble damages and civil penalties under the Iowa False Claims Law, I.C.A. § 685.1, *et seq*.

306. Iowa False Claims Law, I.C.A. § 685.2, in pertinent part provides for liability for any person who:

> (a) Knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval.
>
> (b) Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim.
>
> (c) Conspires to commit a violation of paragraph "a", "b" . . . .

307. Defendants violated the Iowa False Claims Law, I.C.A. § 685.1, *et seq*. and knowingly caused false claims to be made, used and presented to the State of Iowa by their deliberate and systematic violation of federal and state laws and by virtue of the fact that none of the claims submitted in connection with their conduct were even eligible for reimbursement by the government-funded healthcare programs.

308. The State of Iowa, by and through the Iowa Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

309. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was a condition of payment of claims submitted to the State of Iowa in connection with Defendants' conduct. Compliance with applicable Iowa statutes was also a condition of payment of claims submitted to the State of Iowa.

310. Had the State of Iowa known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

311. As a result of Defendants' violations of the Iowa False Claims Law, I.C.A. § 685.1, *et seq*., the State of Iowa has been damaged in an amount far in excess of millions of dollars exclusive of interest.

312. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Iowa False Claims Law, I.C.A. § 685.1, *et seq*., on behalf of himself and the State of Iowa.

313. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Iowa in the operation of its Medicaid program.

Count 18
Louisiana Medical Assistance Programs Integrity Law
(La. Rev. Stat. Ann. § 46:437.1, *et seq*.)

314. Relator repeats and realleges each allegation contained in the preceding paragraphs of this Complaint.

315. This is a *qui tam* action brought by Relator on behalf of the State of Louisiana to recover treble damages and civil penalties under the Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. Ann. § 437.1, *et seq*.

316. La. Rev. Stat. Ann. § 46:438.3 provides:

> (A) No person shall knowingly present or cause to be presented a false or fraudulent claim.
>
> (B) No person shall knowingly engage in misrepresentation or make, use, or cause to be made or used, a false record or statement material to a false or fraudulent claim.
>
> (C) No person shall knowingly make, use, or cause to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the medical assistance programs, or to knowingly conceal, avoid, or decrease an obligation to pay or transmit money or property to the medical assistance programs.
>
> (D) No person shall conspire to defraud, or attempt to defraud, the medical assistance programs through misrepresentation or by obtaining, or attempting to obtain, payment for a false or fraudulent claim.

317. Defendants further violated La. Rev. Stat. Ann. § 46:438.3 and knowingly caused false claims to be made, used and presented to the State of Louisiana by their deliberate and systematic violation of federal and state laws and by virtue of the fact that none of the claims submitted in connection with their conduct were even eligible for reimbursement by the government-funded healthcare programs.

318. The State of Louisiana, by and through the Louisiana Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third-party payers in connection therewith.

319. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and also an express condition of payment of claims submitted to the State of Louisiana in connection with Defendants' conduct. Compliance with

applicable Louisiana statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Louisiana.

320. Had the State of Louisiana known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

321. As a result of Defendants' violations of La. Rev. Stat. Ann. § 46:438.3, the State of Louisiana has been damaged in an amount far in excess of millions of dollars exclusive of interest.

322. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to La. Rev. Stat. Ann. § 46:439.1(A) on behalf of himself and the State of Louisiana.

323. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Louisiana in the operation of its Medicaid program.

Count 19
Massachusetts False Claims Act
(Mass. Gen. Laws Ann. Ch. 12 § 5(A), *et seq.*)

324. Relator repeats and realleges each allegation contained in the preceding paragraphs of this Complaint.

325. This is a *qui tam* action brought by Relator on behalf of the Commonwealth of Massachusetts for treble damages and penalties under Massachusetts False Claims Act, Mass. Gen. Laws Ann. Ch. 12 § 5(A), *et seq*.

326. Mass. Gen. Laws Ann. Ch. 12 § 5B(a) provides liability for any person who:

> (1) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
>
> (2) knowingly makes, uses, or causes to be made or used a false record or statement material to a false or fraudulent claim; or
>
> (3) conspires to commit a violation of this subsection; or
>
> * * *
>
> (10) is a beneficiary of an inadvertent submission of a false claim to the common wealth or political subdivision thereof, or is a beneficiary of an overpayment from the commonwealth or a political subdivision thereof, and who subsequently discovers the falsity of the claim or the receipt of overpayment, and fails to disclose the false claim or receipt of overpayment to the commonwealth or a political subdivision by the later of:
>
> (i) the date which is 60 days after the date on which the false claim or receipt of overpayment was identified; or
>
> (ii) the date any corresponding cost report is due . . . .

327. Defendants violated Mass. Gen. Laws Ann. Ch. 12 § 5B and knowingly caused false claims to be made, used and presented to the Commonwealth of Massachusetts by the conduct alleged herein and by virtue of the fact that none of the claims submitted in connection with their conduct were even eligible for reimbursement by the government-funded healthcare programs.

328. The Commonwealth of Massachusetts, by and through the Massachusetts Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

329. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was a condition of payment of claims submitted to the Commonwealth of Massachusetts in connection with Defendants' conduct. Compliance with applicable

Massachusetts statutes was also a condition of payment of claims submitted to the Commonwealth of Massachusetts.

330. Had the Commonwealth of Massachusetts known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

331. As a result of Defendants' violations of Mass. Gen. Laws Ann. Ch. 12 § 5B, the Commonwealth of Massachusetts has been damaged in an amount far in excess of millions of dollars exclusive of interest.

332. Relator is a private person with direct and independent knowledge of the allegations in this Complaint, who has brought this action pursuant to Mass. Gen. Laws Ann. Ch. 12 § 5(c)(2) on behalf of himself and the Commonwealth of Massachusetts.

333. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the Commonwealth of Massachusetts in the operation of its Medicaid program.

Count 20
Michigan Medicaid False Claims Act
(Mich. Comp. Laws § 400.601, *et seq.*)

334. Relator repeats and realleges each allegation contained in the preceding paragraphs of this Complaint.

335. This is a *qui tam* action brought by Relator on behalf of the State of Michigan to recover treble damages and civil penalties under Michigan Medicaid False Claims Act, Mich. Comp. Laws § 400.603, which provides in pertinent part:

> (1) A person shall not knowingly make or cause to be made a false statement or false representation of a material fact in an application for Medicaid benefits.
>
> (2) A person shall not knowingly make or cause to be made a false statement or false representation of a material fact for use in determining rights to a Medicaid benefit. . . .

336. Defendants violated Michigan law and knowingly caused false claims to be made, used and presented to the State of Michigan by their deliberate and systematic violation of federal and state laws and by virtue of the fact that none of the claims submitted in connection with their conduct were even eligible for reimbursement by the government-funded healthcare programs.

337. The State of Michigan, by and through the Michigan Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

338. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was a condition of payment of claims submitted to the State of Michigan in connection with Defendants' conduct. Compliance with applicable Michigan statutes was also a condition of payment of claims submitted to the State of Michigan.

339. Had the State of Michigan known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

340. As a result of Defendants' violations of the Medicaid False Claims Act, the State of Michigan has been damaged in an amount far in excess of millions of dollars exclusive of interest.

341. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to the Medicaid False Claims Act on behalf of himself and the State of Michigan.

342. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Michigan in the operation of its Medicaid program.

Count 21
Minnesota False Claims Act
(M.S.A. § 15C.01, *et seq.*)

343. Relator repeats and realleges each allegation contained in the preceding paragraphs of this Complaint.

344. This is a *qui tam* action brought by Relator on behalf of the State of Minnesota to recover treble damages and civil penalties under the Minnesota False Claims Act, M.S.A. § 15C.01, *et seq*.

345. Minnesota False Claims Act, M.S.A. § 15C.02, provides for liability for any person who:

> (1) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
>
> (2) knowingly makes or uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
>
> (3) knowingly conspires to commit a violation of clause (1), (2), (4), (5), (6), or (7);
>
> (4) has possession, custody, or control of property or money used, or to be used, by the state or a political subdivision and knowingly delivers

or causes to be delivered less than all of that money or property;

(5) is authorized to make or deliver a document certifying receipt for money or property used, or to be used, by the state or a political subdivision and, intending to defraud the state or a political subdivision, makes or delivers the receipt without completely knowing that the information on the receipt is true;

(6) knowingly buys, or receives as a pledge of an obligation or debt, public property from an officer or employee of the state or a political subdivision who lawfully may not sell or pledge the property; or

(7) knowingly makes or uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the state or a political subdivision, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the state or a political subdivision.

346. Defendants violated the Minnesota False Claims Act and knowingly caused false claims to be made, used and presented to the State of Minnesota by their deliberate and systematic violation of federal and state laws and by virtue of the fact that none of the claims submitted in connection with their conduct were even eligible for reimbursement by the government-funded healthcare programs.

347. The State of Minnesota, by and through the Minnesota Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third-party payers in connection therewith.

348. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was a condition of payment of claims submitted to the State of Minnesota in connection with Defendants' conduct. Compliance with applicable Minnesota statutes was also a condition of payment of claims submitted to the State of Minnesota.

349. Had the State of Minnesota known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were

premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

350. As a result of Defendants' violations of the Minnesota False Claims Act, the State of Minnesota has been damaged in an amount far in excess of millions of dollars exclusive of interest.

351. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to the Minnesota False Claims Act on behalf of himself and the State of Minnesota.

352. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Minnesota in the operation of its Medicaid program.

Count 22
Montana False Claims Act
(MCA § 17-8-401, *et seq.*)

353. Relator repeats and realleges each allegation contained in the preceding paragraphs of this Complaint.

354. This is a *qui tam* action brought by Relator on behalf of the State of Montana to recover treble damages and civil penalties under the Montana False Claims Act, MCA § 17-8-401, *et seq*.

355. Montana's False Claims Act, MCA § 17-8-403, provides for liability for any person who:

(a) knowingly presents or causes to be presented a false or fraudulent claim for payment or approval;

(b) knowingly makes, uses, or causes to be made or used a false record or statement material to a false or fraudulent claim;

(c) conspires to commit a violation of this subsection (1);

(d) has possession, custody, or control of public property or money used or to be used by the governmental entity and knowingly delivers or causes to be delivered less than all of the property or money;

(e) is authorized to make or deliver a document certifying receipt of property used or to be used by the governmental entity and, with the intent to defraud the governmental entity or to willfully conceal the property, makes or delivers a receipt without completely knowing that the information on the receipt is true;

(f) knowingly buys or receives as a pledge of an obligation or debt public property of the governmental entity from any person who may not lawfully sell or pledge the property;

(g) knowingly makes, uses, or causes to be made or used a false record or statement material to an obligation to pay or transmit money or property to a governmental entity or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to a governmental entity; or

(h) as a beneficiary of an inadvertent submission of a false or fraudulent claim to the governmental entity, subsequently discovers the falsity of the claim or that the claim is fraudulent and fails to disclose the false or fraudulent claim to the governmental entity within a reasonable time after discovery of the false or fraudulent claim.

356. Defendants violated the Montana False Claims Act and knowingly caused false claims to be made, used and presented to the State of Montana by their deliberate and systematic violation of federal and state laws and by virtue of the fact that none of the claims submitted in connection with their conduct were even eligible for reimbursement by the government-funded healthcare programs.

357. The State of Montana, by and through the Montana Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third-party payers in connection therewith.

358. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was a condition of payment of claims submitted to the State of Montana in

connection with Defendants' conduct. Compliance with applicable Montana statutes was also a condition of payment of claims submitted to the State of Montana.

359. Had the State of Montana known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

360. As a result of Defendants' violations of the Montana False Claims Act, the State of Montana has been damaged in an amount far in excess of millions of dollars exclusive of interest.

361. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to the Montana False Claims Act on behalf of himself and the State of Montana.

362. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Montana in the operation of its Medicaid program.

Count 23
Nevada False Claims Act
(Nev. Rev. Stat. Ann. § 357.010, *et seq.*)

363. Relator repeats and realleges each allegation contained in the preceding paragraphs of this Complaint.

364. This is a *qui tam* action brought by Relator on behalf of the State of Nevada to recover treble damages and civil penalties under the Nevada False Claims Act, Nev. Rev. Stat. Ann. § 357.010, *et seq*.

365. N.R.S. § 357.040(1) provides liability for any person who:

(a) Knowingly presents or causes to be presented a false or fraudulent claim for payment or approval.

(b) Knowingly makes or uses, or causes to be made or used, a false record or statement that is material to a false or fraudulent claim.

(c) Has possession, custody or control of public property or money used or to be used by the State or a political subdivision and knowingly delivers or causes to be delivered to the State or a political subdivision less money or property than the amount of which the person has possession, custody or control.

(d) Is authorized to prepare or deliver a document that certifies receipt of money or property used or to be used by the State or a political subdivision and knowingly prepares or delivers such a document without knowing that the information on the document is true.

(e) Knowingly buys, or receives as a pledge or security for an obligation or debt, public property from a person who is not authorized to sell or pledge the property.

(f) Knowingly makes or uses, or causes to be made or used, a false record or statement that is material to an obligation to pay or transmit money or property to the State or a political subdivision.

(g) Knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the State or a political subdivision.

(h) Is a beneficiary of an inadvertent submission of a false claim and, after discovering the falsity of the claim, fails to disclose the falsity to the State or political subdivision within a reasonable time.

(i) Conspires to commit any of the acts set forth in this subsection.

366. Defendants violated N.R.S. § 357.040(1) and knowingly caused false claims to be made, used and presented to the State of Nevada by their deliberate and systematic violation of federal and state laws and by virtue of the fact that none of the claims submitted in connection with their conduct were even eligible for reimbursement by the government-funded healthcare programs.

367. The State of Nevada, by and through the Nevada Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third-party payers in connection therewith.

368. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was a condition of payment of claims submitted to the State of Nevada in connection with Defendants' conduct. Compliance with applicable Nevada statutes was also a condition of payment of claims submitted to the State of Nevada.

369. Had the State of Nevada known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

370. As a result of Defendants' violations of N.R.S. § 357.040(1), the State of Nevada has been damaged in an amount far in excess of millions of dollars exclusive of interest.

371. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to N.R.S. § 357.080(1) on behalf of himself and the State of Nevada.

372. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Nevada in the operation of its Medicaid program.

Count 24
New Hampshire Medicaid Fraud and False Claims Act
(N.H. R.S.A. Title 22, Ch. 167, *et seq.*)

373. Relator repeats and realleges each allegation contained in the preceding paragraphs of this Complaint.

374. This is a *qui tam* action brought by Relator on behalf of the State of New Hampshire to recover treble damages and civil penalties under the Medicaid Fraud and False Claims Act, R.S.A. §§ 167:58, *et seq*.

375. Under R.S.A. § 167:61-b, no person shall:

(a) Knowingly presents, or causes to be presented, to an officer or employee of the department, a false or fraudulent claim for payment or approval.

(b) Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the department.

(c) Conspires to defraud the department by getting a false or fraudulent claim allowed or paid.

(d) Has possession, custody, or control of property or money used, or to be used, by the department and, intending to defraud the department or willfully to conceal the property, delivers, or causes to be delivered, less property than the amount for which the person receives a certificate or receipt.

(e) Knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the department.

(f) Is a beneficiary of an inadvertent submission of a false claim to the department, who subsequently discovers the falsity of the claim, and fails to disclose the false claim to the department within a reasonable time after discovery of the false claim.

376. Defendants violated R.S.A. § 167:61-b, and knowingly caused false claims to be made, used and presented to the State of New Hampshire by their deliberate and systematic violation of federal and state laws and by virtue of the fact that none of the claims submitted in connection with their conduct were even eligible for reimbursement by the government-funded healthcare programs.

377. The State of New Hampshire, by and through the New Hampshire Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third-party payers in connection therewith.

378. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was a condition of payment of claims submitted to the State of New Hampshire in connection with Defendants' conduct. Compliance with applicable New Hampshire statutes was also a condition of payment of claims submitted to the State of New Hampshire.

379. Had the State of New Hampshire known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

380. As a result of Defendants' violations of R.S.A. § 167:61-b, the State of New Hampshire has been damaged in an amount far in excess of millions of dollars exclusive of interest.

381. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to R.S.A. § 167:61-c (II), on behalf of himself and the State of New Hampshire.

382. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of New Hampshire in the operation of its Medicaid program.

Count 25
New Jersey False Claims Act
(N.J.S.A. § 2A:32C-1, *et seq.*)

383. Relator repeats and realleges each allegation contained in the preceding paragraphs of this Complaint.

384. This is a *qui tam* action brought by Relator on behalf of the State of New Jersey to recover treble damages and civil penalties under the New Jersey False Claims Act, N.J.S.A. § 2A:32C-1, *et seq*.

385. N.J.S.A. § 2A:32C-3, provides for liability for any person who:

(a) Knowingly presents or causes to be presented to an employee, officer or agent of the State, or to any contractor, grantee, or other recipient of State funds, a false or fraudulent claim for payment or approval;

(b) Knowingly makes, uses, or causes to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the State;

(c) Conspires to defraud the State by getting a false or fraudulent claim allowed or paid by the State;

(d) Has possession, custody, or control of public property or money used or to be used by the State and knowingly delivers or causes to be delivered less property than the amount for which the person receives a certificate or receipt;

(e) Is authorized to make or deliver a document certifying receipt of property used or to be used by the State and, intending to defraud the entity, makes or delivers a receipt without completely knowing that the information on the receipt is true;

(f) Knowingly buys, or receives as a pledge of an obligation or debt, public property from any person who lawfully may not sell or pledge the property; or

(g) Knowingly makes, uses, or causes to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State.

386. Defendants violated the New Jersey False Claims Act and knowingly caused false claims to be made, used and presented to the State of New Jersey by their deliberate and systematic violation of federal and state laws and by virtue of the fact that none of the claims submitted in connection with their conduct were even eligible for reimbursement by the government-funded healthcare programs.

387. The State of New Jersey, by and through the New Jersey Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third-party payers in connection therewith.

388. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was a condition of payment of claims submitted to the State of New Jersey in connection with Defendants' conduct. Compliance with applicable New Jersey statutes was also a condition of payment of claims submitted to the State of New Jersey.

389. Had the State of New Jersey known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

390. As a result of Defendants' violations of the New Jersey False Claims Act, the State of New Jersey has been damaged in an amount far in excess of millions of dollars exclusive of interest.

391. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to the New Jersey False Claims Act on behalf of himself and the State of New Jersey.

392. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of New Jersey in the operation of its Medicaid program.

Count 26
New Jersey Medical Assistance & Health Services Act
(N.J.S.A. 30:4D-1, *et seq.*)

393. Relator repeats and realleges each allegation contained in the preceding paragraphs of this Complaint.

394. The New Jersey Medical Assistance and Health Services Act ("NJMAHS"), N.J.S.A. 30:4D-1, *et seq.*, is aimed at providing medical assistance to residents with limited resources, but also provides FCA-like protections in the event of a violation.

395. Pursuant to N.J.S.A. 30:4D-17(b), it is illegal for any provider, or any person, firm, partnership, or entity to:

> (1) Knowingly and willfully make or cause to be made any false statement or representation of a material fact in any cost study, claim form, or any document necessary to apply for or receive any benefit or payment under P.L.1968, c.413; or
>
> (2) At any time knowingly and willfully make or cause to be made any false statement, written or oral, of a material fact for use in determining rights to such benefit or payment under P.L.1968, c.413; or
>
> (3) Conceal or fail to disclose the occurrence of an event which
>
> (i) affects a person's initial or continued right to any such benefit or payment, or
>
> (ii) affects the initial or continued right to any such benefit or payment of any provider or any person, firm, partnership, corporation, or other entity in whose behalf a person has applied for or is receiving such benefit or payment with an intent to fraudulently secure benefits or payments not authorized under P.L.1968, c.413 or in a greater amount than that which is authorized under P.L.1968, c.413; or
>
> (4) Knowingly and willfully convert benefits or payments or any part thereof

> received for the use and benefit of any provider or any person, firm, partnership, corporation, or other entity to a use other than the use and benefit of such provider or such person, firm, partnership, corporation, or entity . . . .

396. In addition to any other penalties provided by law, violators of the NJMAHS shall be liable for civil penalties of: (1) payment of interest on the amount of the excess benefits or payments at the maximum legal rate in effect on the date the payment was made; (2) payment of an amount not to exceed three-fold the amount of such excess benefits or payments; and (3) payment in the sum of not less than and not more than the civil penalty allowed under the federal False Claims Act, as it may be adjusted for inflation, for each claim for assistance, benefits or payment. N.J.S.A. 30:4D-17(e).

397. In this matter, Defendants submitted bills to the New Jersey State Government for payment and retained improperly obtained payments arising from their illegal kickback scheme. All such false claims were knowingly submitted to get false or fraudulent claims paid or approved by the New Jersey State Government.

398. As a result of Defendants' acts, the State of New Jersey has been damaged, and continues to be damaged, in a substantial amount to be determined at trial, and the State of New Jersey is entitled to penalty of not less than $11,665 and not more than $23,331 for each false or fraudulent claim, plus three times the amount of damages which the State sustains arising from Defendants' unlawful conduct as described herein

Count 27
New Mexico Medicaid False Claims Act
(N.M. Stat. Ann. § 27-14-1, *et seq.*)
New Mexico Fraud Against Taxpayers Act
(N.M. Stat. Ann. § 44-9-1, *et seq.*)

399. Relator repeats and realleges each allegation contained in the preceding paragraphs of this Complaint.

400. This is a *qui tam* action brought by Relator on behalf of the State of New Mexico to recover treble damages and civil penalties under the New Mexico Fraud Against Taxpayers Act, which provides in pertinent part:

> A person shall not:
>
> (1) knowingly present, or cause to be presented, to an employee, officer or agent of the state or a political subdivision or to a contractor, grantee, or other recipient of state funds or political subdivision funds a false or fraudulent claim for payment or approval;
>
> (2) knowingly make or use, or cause to be made or used, a false, misleading or fraudulent record or statement to obtain or support the approval of or the payment on a false or fraudulent claim; or
>
> (3) conspire to defraud the state or a political subdivision by obtaining approval or payment on a false or fraudulent claim . . . .
>
> N.M. Stat. Ann. § 44-9-3(A)(1)-(3).

401. Defendants violated N.M. Stat. Ann. §§ 27-14-1, *et seq*. and N.M. Stat. Ann. § 44-9-1 *et seq*. and knowingly caused false claims to be made, used and presented to the State of New Mexico by their deliberate and systematic violation of federal and state laws and by virtue of the fact that none of the claims submitted in connection with their conduct were even eligible for reimbursement by the government-funded healthcare programs.

402. The State of New Mexico, by and through the New Mexico Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third-party payers in connection therewith.

403. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was a condition of payment of claims submitted to the State of New Mexico in connection with Defendants' conduct. Compliance with applicable New Mexico statutes was also a condition of payment of claims submitted to the State of New Mexico.

404. Had the State of New Mexico known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

405. As a result of Defendants' violations of N.M. Stat. Ann. §§ 27-14-1 *et seq*. and N.M. Stat. Ann. § 44-9-1 *et seq*., the State of New Mexico has been damaged in an amount far in excess of millions of dollars exclusive of interest.

406. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to N.M. Stat. Ann. §§ 27-14-1, et *seq*. and N.M. Stat. Ann. § 44-9-1, *et seq*. on behalf of himself and the State of New Mexico.

407. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of New Mexico in the operation of its Medicaid program.

Count 28
New York False Claims Act
(N.Y. State Fin. Law § 187, *et seq*.)

408. Relator repeats and realleges each allegation contained in the preceding paragraphs of this Complaint.

409. This is a *qui tam* action brought by Relator and the State of New York to recover treble damages and civil penalties under the New York False Claims Act, N.Y. State Fin. Law§ 187, *et seq*.

410. N.Y. State Fin. Law§ 189 provides liability for any person who-

a. knowingly presents, or causes to be presented, to any employee, officer or agent of the state or a local government, a false or fraudulent claim for payment or approval;

b. knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the state or a local government;

c. conspires to defraud the state or a local government by getting a false or fraudulent claim allowed or paid.

411. Defendants knowingly violated N.Y. State Fin. Law § 189 and knowingly caused thousands of false claims to be made, used and presented to the State of New York during the Covered Period by violating the Federal Anti-Kickback Act, as described herein.

412. As a result of Defendants' kickback schemes, all of the claims that Defendants knowingly caused facilities, physicians and radiologists to knowingly submit to the New York Medicaid program are false or fraudulent. Further, Defendants knowingly caused facilities, physicians and radiologists to falsely certify, expressly and/or impliedly, and represent full compliance with all federal and state laws and regulations prohibiting fraudulent acts and false reporting, including but not limited to the Federal Anti-Kickback Statute. Compliance with federal and state laws and regulations was a condition of payment.

413. The State of New York, by and through the New York Medicaid program and other state health care programs, paid the false and/or fraudulent claims.

414. Given the structure of the health care systems, the false statements, representations, and records made by Defendants had the potential to influence the State of New York's payment decision

415. The ultimate submission by facilities, physicians, radiologists, and third-party payers of false and/or fraudulent claims to the state Medicaid program was a foreseeable factor in the State of New York's loss, and a consequence of the scheme.

416. As a result of Defendants' violations of N.Y. State Fin. Law§ 189, the State of New York has been damaged.

417. There are no bars to recovery under N.Y. Fin. Law § 190(9) and, or in the alternative, Relator is an original source as defined therein. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to N.Y. State Fin. Law§ 190(2) on behalf of himself and the State of New York.

418. This Court is requested to accept pendent jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of New York in the operation of its Medicaid program.

Count 29
North Carolina False Claims Act
N.C. Gen. Stat. Ann. § 1-605, *et seq.*)

419. Relator repeats and realleges each allegation contained in the preceding paragraphs of this Complaint.

420. This is a *qui tam* action brought by Relator on behalf of the State of North Carolina to recover treble damages and civil penalties under the North Carolina False Claims Act, N.C. Gen. Stat. Ann. § 1-605, *et seq*.

421. North Carolina's False Claims Act, N.C.G.S.A. § 1-607(a), provides for liability for any person who:

> (1) Knowingly presents or causes to be presented a false or fraudulent claim for payment or approval.
>
> (2) Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim.
>
> (3) Conspires to commit a violation of subdivision (1), (2), (4), (5), (6), or (7) of this section.
>
> (4) Has possession, custody, or control of property or money used or to be used by the State and knowingly delivers or causes to be delivered less

than all of that money or property.

(5) Is authorized to make or deliver a document certifying receipt of property used or to be used by the State and, intending to defraud the State, makes or delivers the receipt without completely knowing that the information on the receipt is true.

(6) Knowingly buys, or receives as a pledge of an obligation or debt, public property from any officer or employee of the State who lawfully may not sell or pledge the property.

(7) Knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the State, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the State.

422. Defendants violated the North Carolina False Claims Act, and knowingly caused false claims to be made, used and presented to the State of North Carolina by their deliberate and systematic violation of federal and state laws and by virtue of the fact that none of the claims submitted in connection with their conduct were even eligible for reimbursement by the government-funded healthcare programs.

423. The State of North Carolina, by and through the North Carolina Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third-party payers in connection therewith.\

424. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and an express condition of payment of claims submitted to the State of North Carolina in connection with Defendants' conduct. Compliance with applicable North Carolina statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of North Carolina.

425. Had the State of North Carolina known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants'

conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

426. As a result of Defendants' violations of the North Carolina False Claims Act, the State of North Carolina has been damaged in an amount far in excess of millions of dollars exclusive of interest.

427. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to the North Carolina False Claims Act on behalf of himself and the State of North Carolina.

428. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of North Carolina in the operation of its Medicaid program.

Count 30
Oklahoma Medicaid False Claims Act
Okl. Stat. Ann. Tit. 63, § 5053, *et seq.*)

429. Relator repeats and realleges each allegation contained in the preceding paragraphs of this Complaint.

430. This is a *qui tam* action brought by Relator on behalf of the State of Oklahoma to recover treble damages and civil penalties under the Oklahoma Medicaid False Claims Act, 63 Okl. Stat. Ann. Tit. 63, § 5053, *et seq*.

431. Oklahoma's Medicaid False Claims Act, 63 Okl. St. Ann. § 5053.1, provides for liability for any person who:

> (1) Knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
>
> (2) Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;

(3) Conspires to commit a violation of the Oklahoma Medicaid False Claims Act;

(4) Has possession, custody, or control of property or money used, or to be used, by the state knowingly delivers, or causes to be delivered, less than all of such money or property;

(5) Is authorized to make or deliver a document certifying receipt of property used or to be used by the state and, intending to defraud the state, makes or delivers the receipt without completely knowing that the information on the receipt is true;

(6) Knowingly buys or receives as a pledge of an obligation or debt, public property from an officer or employee of the state who lawfully may not sell or pledge the property; or

(7) Knowingly makes, uses or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the state, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the state.

432. Defendants violated the Oklahoma Medicaid False Claims Act and knowingly caused false claims to be made, used and presented to the State of Oklahoma by their deliberate and systematic violation of federal and state laws and by virtue of the fact that none of the claims submitted in connection with their conduct were even eligible for reimbursement by the government-funded healthcare programs.

433. The State of Oklahoma, by and through the Oklahoma Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third-party payers in connection therewith.

434. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and also an express condition of payment of claims submitted to the State of Oklahoma in connection with Defendants' conduct. Compliance with applicable Oklahoma statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Oklahoma.

435. Had the State of Oklahoma known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

436. As a result of Defendants' violations of the Oklahoma Medicaid False Claims Act, the State of Oklahoma has been damaged in an amount far in excess of millions of dollars exclusive of interest.

437. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to the Oklahoma Medicaid False Claims Act on behalf of himself and the State of Oklahoma. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Oklahoma in the operation of its Medicaid program.

Count 31
Rhode Island False Claims Act
(R.I. Gen. Laws § 9-1.1-1, *et seq.*)

438. Relator repeats and realleges each allegation contained in the preceding paragraphs of this Complaint.

439. This is a *qui tam* action brought by Relator on behalf of the State of Rhode Island to recover treble damages and civil penalties under the Rhode Island False Claims Act, R.I. Gen. Laws § 9-1.1-1, *et seq*.

440. Rhode Island's False Claims Act, Gen. Laws 1956, § 9-1.1-3, provides for liability for any person who:

(1) Knowingly presents, or causes to be presented a false or fraudulent claim for payment or approval;

(2) Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;

(3) Conspires to commit a violation of subdivisions 9-1.1-3(1), (2), (3), (4), (5), (6) or (7);

(4) Has possession, custody, or control of property or money used, or to be used, by the state and knowingly delivers, or causes to be delivered, less property than all of that money or property;

(5) Is authorized to make or deliver a document certifying receipt of property used, or to be used, by the state and, intending to defraud the state, makes or delivers the receipt without completely knowing that the information on the receipt is true;

(6) Knowingly buys, or receives as a pledge of an obligation or debt, public property from an officer or employee of the state, or a member of the guard, who lawfully may not sell or pledge the property; or

(7) Knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the state, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the state.

441. Defendants violated the Rhode Island False Claims Act and knowingly caused false claims to be made, used and presented to the State of Rhode Island by their deliberate and systematic violation of federal and state laws and by virtue of the fact that none of the claims submitted in connection with their conduct were even eligible for reimbursement by the government-funded healthcare programs.

442. The State of Rhode Island, by and through the Rhode Island Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

443. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and also an express condition of payment of claims

submitted to the State of Rhode Island in connection with Defendants' conduct. Compliance with applicable Rhode Island statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Rhode Island.

444. Had the State of Rhode Island known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

445. As a result of Defendants' violations of the Rhode Island False Claims Act, the State of Rhode Island has been damaged in an amount far in excess of millions of dollars exclusive of interest.

446. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to the Rhode Island False Claims Act on behalf of himself and the State of Rhode Island.

447. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Rhode Island in the operation of its Medicaid program.

Count 32
Tennessee Medicaid False Claims Act
(Tenn. Code Ann. § 71-5-181, *et seq.*)

448. Relator repeats and realleges each allegation contained in the preceding paragraphs of this Complaint.

449. This is a *qui tam* action brought by Relator on behalf of the State of Tennessee to recover treble damages and civil penalties under the Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-181, *et seq*.

450. Section 71-5-182(a)(1) provides liability for any person who:

> (1) Knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval under the Medicaid program;
>
> (2) Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim under the Medicaid program;
>
> (3) Conspires to commit a violation of subdivision (a)(1)(A), (a)(1)((B), or (a)(1)((D); or
>
> (4) Knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money, or property to the state, or knowingly conceals, or knowingly and improperly, avoids, or decreases an obligation to pay or transmit money or property to the state, relative to the Medicaid program.

451. Defendants violated Tenn. Code Ann. § 71-5-1 82(a)(1) and knowingly caused false claims to be made, used and presented to the State of Tennessee by the conduct alleged herein and by virtue of the fact that none of the claims submitted in connection with their conduct were even eligible for reimbursement by the government-funded healthcare programs.

452. The State of Tennessee, by and through the Tennessee Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

453. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was a condition of payment of claims submitted to the State of Tennessee in connection with Defendants' conduct. Compliance with applicable Tennessee statutes was also a condition of payment of claims submitted to the State of Tennessee.

454. Had the State of Tennessee known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

455. As a result of Defendants' violations of Tenn. Code Ann. § 71-5-182(a)(1), the State of Tennessee has been damaged in an amount far in excess of millions of dollars exclusive of interest.

456. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Tenn. Code Ann. § 71-5-183(a)(1) on behalf of himself and the State of Tennessee.

457. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Tennessee in the operation of its Medicaid program.

Count 33
Texas False Claims Act
(Tex. Hum. Res. Code § 36.001, *et seq.*)

458. Relator repeats and realleges each allegation contained in the preceding paragraphs of this Complaint.

459. This is a *qui tam* action brought by Relator on behalf of the State of Texas to recover double damages and civil penalties under Tex. Hum. Res. Code § 36.001, *et seq*.

460. Tex. Hum. Res. Code § 36.002 provides liability for any person who:

> (1) knowingly makes or causes to be made a false statement or misrepresentation of a material fact to permit a person to receive a benefit or payment under the Medicaid program that is not authorized or that is greater than the benefit or payment that is

authorized;

(2) knowingly conceals or fails to disclose information that permits a person to receive a benefit or payment under the Medicaid program that is not authorized or that is greater than the benefit or payment that is authorized;

(3) knowingly applies for and receives a benefit or payment on behalf of another person under the Medicaid program and converts any part of the benefit or payment to a use other than for the benefit of the person on whose behalf it was received;

(4) knowingly makes, causes to be made, induces, or seeks to induce the making of a false statement or misrepresentation of material fact concerning:

a. the conditions or operation of a facility in order that the facility may qualify for certification or recertification required by the Medicaid program, including certification or recertification as . . .

b. information required to be provided by a federal or state law, rule, regulation, or provider agreement pertaining to the Medicaid program;

(5) except as authorized under the Medicaid program, knowingly pays, charges, solicits, accepts, or receives, in addition to an amount paid under the Medicaid program, a gift, money, a donation, or other consideration as a condition to the provision of a service or product or the continued provision of a service or product if the cost of the service or product is paid for, in whole or in part, under the Medicaid program;

(6) knowingly presents or causes to be presented a claim for payment under the Medicaid program for a product provided or a service rendered by a person who:

a. is not licensed to provide the product or render the service, if a license is required; or

b. is not licensed in the manner claimed;

(7) knowingly makes or causes to be made a claim under the Medicaid program for:

a. a service or product that has not been approved or acquiesced in by a treating physician or health care practitioner;

b. a service or product that is substantially inadequate or inappropriate when compared to generally recognized standards within the particular discipline or within the health care industry; or

c. a product that has been adulterated, debased, mislabeled, or that is otherwise inappropriate;

(8) makes a claim under the Medicaid program and knowingly fails to indicate the type of license and the identification number of the licensed health care provider who actually provided the service;

(9) conspires to commit a violation of Subdivision (1), (2), (3), (4), (5), (6), (7), (8), (10), (11), (12), or (13);

(10) is a managed care organization that contracts with the commission or other state agency to provide or arrange to provide health care benefits or services to individuals eligible under the Medicaid program and knowingly:

a. fails to provide to an individual a health care benefit or service that the organization is required to provide under the contract;

b. fails to provide to the commission or appropriate state agency information required to be provided by law, commission or agency rule, or contractual provision; or

c. engages in a fraudulent activity in connection with the enrollment of an individual eligible under the Medicaid program in the organization's managed care plan or in connection with marketing the organization's services to an individual eligible under the Medicaid program;

(11) knowingly obstructs an investigation by the attorney general of an alleged unlawful act under this section;

(12) knowingly makes, uses, or causes the making or use of a false record or statement material to an obligation to pay or transmit money or property to this state under the Medicaid program, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to this state under the Medicaid program; or

(13) knowingly engages in conduct that constitutes a violation under Section 32.039(b).

461. Defendants violated Tex. Hum. Res. Code § 36.002 and knowingly caused false claims to be made, used and presented to the State of Texas by engaging in the conduct alleged herein and by virtue of the fact that none of the claims submitted in connection with their conduct were even eligible for reimbursement by the government-funded healthcare programs.

462. The State of Texas, by and through the Texas Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third-party payers in connection therewith.

463. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was a condition of payment of claims submitted to the State of Texas in connection with Defendants' conduct. Compliance with applicable Texas statutes was also a condition of payment of claims submitted to the State of Texas.

464. Had the State of Texas known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

465. As a result of Defendants' violations of Tex. Hum. Res. Code § 36.002, the State of Texas has been damaged in an amount far in excess of millions of dollars exclusive of interest.

466. Defendants did not, within 30 days after they first obtained information as to such violations, furnish such information to officials of the State responsible for investigating false claims violations, did not otherwise fully cooperate with any investigation of the violations, and has not otherwise furnished information to the State regarding the claims for reimbursement at issue.

467. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Tex. Hum. Res. Code § 36.101 on behalf of himself and the State of Texas.

468. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Texas in the operation of its Medicaid program.

Count 34
Vermont False Claims Act
(Vt. Stat. Ann. tit. 32, § 630, *et seq.*)

469. Relator repeats and realleges each allegation contained in the preceding paragraphs of this Complaint.

470. This is a *qui tam* action brought by Relator on behalf of the State of Vermont to recover treble damages and civil penalties under the Vermont False Claims Act, Vt. Stat. Ann. tit. 32, § 630, *et seq*.

471. Vt. Stat. Ann. tit. 32, § 631(a) in pertinent part provides for liability for any person who:

> (1) knowingly present, or cause to be presented, a false or fraudulent claim for payment or approval;
>
> (2) knowingly make, use, or cause to be made or used, a false record or statement material to a false or fraudulent claim;
>
> (3) knowingly present, or cause to be presented, a claim that includes items or services resulting from a violation of 13 V.S.A. chapter 21 or section 1128B of the Social Security Act, 42 U.S.C. §§ 1320a-7b;
>
> (4) knowingly present, or cause to be presented, a claim that includes items or services for which the State could not receive payment from the federal government due to the operation of 42 U.S.C. § 1396b(s) because the claim includes designated health services (as defined in 42 U.S.C. § 1395nn(h)(6)) furnished to an individual on the basis of a referral that would result in the

> denial of payment under 42 U.S.C. chapter 7, subchapter XVIII (the "Medicare program"), due to a violation of 42 U.S.C. § 1395nn;
>
> * * *
>
> (9) knowingly make, use or cause to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the State;
>
> (10) knowingly conceal or knowingly and improperly avoid or decrease an obligation to pay or transmit money or property to the State; or
>
> * * *
>
> (12) conspire to commit a violation of this subsection.

472. Defendants violated the Vt. Stat. Ann. tit. 32, § 630, *et seq.*, and knowingly caused false claims to be made, used and presented to the State of Vermont by their deliberate and systematic violation of federal and state laws and by virtue of the fact that none of the claims submitted in connection with their conduct were even eligible for reimbursement by the government-funded healthcare programs.

473. The State of Vermont, by and through the Vermont Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third-party payers in connection therewith.

474. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and also an express condition of payment of claims submitted to the State of Vermont in connection with Defendants' conduct. Compliance with applicable Vermont statutes and regulations was also an express condition of payment of claims submitted to the State of Vermont.

475. Had the State of Vermont known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct

failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

476. As a result of Defendants' violations of the Vt. Stat. Ann. tit. 32, § 630, *et seq.*, the State of Vermont has been damaged in an amount far in excess of millions of dollars exclusive of interest.

477. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to the Vt. Stat. Ann. tit. 32, § 630, *et seq*., on behalf of himself and the State of Vermont.

478. This Court is requested to accept pendent jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Vermont in the operation of its Medicaid program.

Count 35
Virginia Fraud Against Taxpayers Act
(Va. Code Ann. § 8.01-216.1, *et seq*.)

479. Relator repeats and realleges each allegation contained in the preceding paragraphs of this Complaint.

480. This is a *qui tam* action brought by Relator on behalf of the Commonwealth of Virginia for treble damages and penalties under Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.3(A), which provides liability for any person who:

> (1) Knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
>
> (2) Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
>
> (3) Conspires to commit a violation of subdivision 1, 2, 4, 5, 6, or 7; or
>
> * * *

> (7) Knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Commonwealth or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Commonwealth.

481. Defendants furthermore violated Virginia's Fraud Against Tax Payers Act, § 8.01-216.3(A), and knowingly caused false claims to be made, used and presented to the Commonwealth of Virginia by their deliberate and systematic violation of federal and state laws and by virtue of the fact that none of the claims submitted in connection with their conduct were even eligible for reimbursement by the government-funded healthcare programs.

482. The Commonwealth of Virginia, by and through the Virginia Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

483. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and also an express condition of payment of claims submitted to the Commonwealth of Virginia in connection with Defendants' conduct. Compliance with applicable Virginia statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the Commonwealth of Virginia.

484. Had the Commonwealth of Virginia known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

485. As a result of Defendants' violations of Virginia's Fraud Against Tax Payers Act, §8.01-216.3a, the Commonwealth of Virginia has been damaged in an amount far in excess of millions of dollars exclusive of interest.

486. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Virginia's Fraud Against Tax Payers Act, §8.01-216.3, on behalf of himself and the Commonwealth of Virginia.

487. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the Commonwealth of Virginia in the operation of its Medicaid program.

Count 36
Washington Medicaid Fraud Act
(Wash. Rev. Code Ann. § 74.66.005, *et seq*.)

488. Relator repeats and realleges each allegation contained in the preceding paragraphs of this Complaint.

489. This is a *qui tam* action brought by Relator on behalf of the State of Washington to recover treble damages and civil penalties under the Washington Medicaid Fraud Act, Wash. Rev. Code Ann. § 74.66.005, *et seq*.

490. RCWA 74.66.020(1) in pertinent part provides for liability for any person who:

> (a) Knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
>
> (b) Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; or
>
> (c) Conspires to commit one or more of the violations in this subsection (1).

491. Defendants violated the Washington Medicaid Fraud Act, Wash. Rev. Code Ann. § 74.66.005, *et seq*., and knowingly caused false claims to be made, used and presented to the

State of Washington by their deliberate and systematic violation of federal and state laws and by virtue of the fact that none of the claims submitted in connection with their conduct were even eligible for reimbursement by the government-funded healthcare programs.

492. The State of Washington, by and through the Washington Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third-party payers in connection therewith.

493. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and also an express condition of payment of claims submitted to the State of Washington in connection with Defendants' conduct. Compliance with applicable Washington statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Washington.

494. Had the State of Washington known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

495. As a result of Defendants' violations of the Washington Medicaid Fraud Act, Wash. Rev. Code Ann. § 74.66.005, *et seq.*, the State of Washington has been damaged in an amount far in excess of millions of dollars exclusive of interest.

496. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to the Washington Medicaid Fraud Act, Wash. Rev. Code Ann. § 74.66.005, *et seq*. on behalf of himself and the State of Washington.

497. This Court is requested to accept pendent jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Washington in the operation of its Medicaid program.

Count 37
Puerto Rico
False Claims to Government of Puerto Rico Programs, Contracts and Services Act (32 L.P.R.A. § 2931, *et seq.*)

498. Relator repeats and realleges each allegation contained in the preceding paragraphs of this Complaint.

499. This is a *qui tam* action brought by Relator on behalf of the Commonwealth of Puerto Rico to recover treble damages and civil penalties under the False Claims to Government of Puerto Rico Programs, Contracts and Services Act, 32 L.P.R.A § 2931, *et seq*.

500. 32 L.P.R.A. § 2934 in pertinent part provides liability for any person who:

> (a) Knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval of benefits under any Government Program or under a service contract;
>
> (b) Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim under any Government Program or under a service contract;
>
> (c) Conspires to commit a violation of clauses (a) and (b) of this subsection; and/or
>
> (d) Knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property, relating to any Government Program or any service contract, as defined in this chapter . . .

501. Defendants violated the False Claims to Government of Puerto Rico Programs, Contracts and Services Act, 32 L.P.R.A § 2931, *et seq.*, and knowingly caused false claims to be made, used and presented to the Commonwealth of Puerto Rico by their deliberate and systematic violation of federal and state laws and by virtue of the fact that none of the claims

submitted in connection with their conduct were even eligible for reimbursement by the government-funded healthcare programs.

502. The Commonwealth of Puerto Rico, by and through the Puerto Rico Medicaid program and other healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third-party payers in connection therewith.

503. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and also an express condition of payment of claims submitted to the Commonwealth of Puerto Rico in connection with Defendants' conduct. Compliance with applicable Puerto Rico statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the Commonwealth of Puerto Rico.

504. Had the Commonwealth of Puerto Rico known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the government-funded healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

505. As a result of Defendants' violations of the False Claims to Government of Puerto Rico Programs, Contracts and Services Act, 32 L.P.R.A § 2931, *et seq.*, the Commonwealth of Puerto Rico has been damaged in an amount far in excess of millions of dollars exclusive of interest.

506. Relator is a private person with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to the False Claims to

Government of Puerto Rico Programs, Contracts and Services Act, 32 L.P.R.A § 2934a(2), on behalf of himself and Commonwealth of Puerto Rico.

507. This Court is requested to accept pendent jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the Commonwealth of Puerto Rico in the operation of its Medicaid program.

Count 38
District of Columbia False Claims Law
(D.C. Code § 2-381.01, *et seq.* (2014)

508. Relator repeats and realleges each allegation contained in the preceding paragraphs of this Complaint.

509. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the District of Columbia Government for payment or approval.

510. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, to induce the District of Columbia Government to approve and pay such false and fraudulent claims.

511. By virtue of the acts described above, Defendants conspired to violate the District of Columbia False Claims Act.

512. The District of Columbia Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for the acts and/or conduct of Defendants as alleged herein.

513. Defendants knowingly submitted and/or caused to be made or used false records or false statements in order to avoid or decrease their obligations to return overpayments of local and federal funds to the District of Columbia.

514. By reason of the Defendants' acts, the District of Columbia has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

515. Pursuant to D.C. Code Ann. § 2-308.02, the District of Columbia is entitled to three times the amount of actual damages plus a penalty of not less than $11,665 and not more than $23,331, as adjusted pursuant to D.C. Code Ann. § 2-308.10, for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

Count 39
Fraud
(Common Law)

516. Relator repeats and realleges each allegation contained in the preceding paragraphs of this Complaint.

517. Defendants sold and purchased Contrast Media Products and Consumables through a kickback scheme, with the intent to conceal their misconduct through fraudulent reporting, misrepresentations and material omissions so that Government Programs and private insurers would direct payment to them which they knew they were not entitled to receive.

518. Government Programs and private insurers issue payments based on voluntary submissions by service providers; the Programs' and private insurers' reliance on the representations in such submissions is not only justifiable, therefore, but also necessary for their fundamental operation.

519. As a result of Defendants' misrepresentations and omissions, the United States, the various FCA States discussed herein, and private insurance companies and their policyholders have been damaged, and continue to be damaged, in an amount to be determined at trial.

Count 40
Unjust Enrichment
(Common Law)

520. Relator repeats and realleges each allegation contained in the preceding paragraphs of this Complaint.

521. Defendants have been unjustly enriched by collecting and keeping compensation in cash and kind that they knew to be prohibited under the FCA, state-level FCAs, CMPL, CIFPA, IICFPA, and regulatory guidance, and which would not have been paid to Defendants but for their illegal submission of false claims to Government Programs and private insurers.

522. Defendants were not entitled to any payment for Contrast Media Agents and related services procured by kickbacks and concealed by misleading statements and reporting omissions. The Government and private insurers are entitled to, and equity and good conscience demand, the return of such payments.

IX. PRAYER FOR RELIEF

WHEREFORE, on each of these claims, Relator requests the following relief be ordered:

As to the Federal FCA Claims:

A. Pursuant to 31 U.S.C. § 3729(a), Defendants pay an amount equal to three times the amount of damages the United States Government has sustained because of Defendants' actions, which Relator currently estimates to be in the tens of millions of dollars, plus a civil penalty of $22,927 for each false or fraudulent claim or such other penalty as the law may permit and/or require for each violation of the FCA;

B. Relator be awarded the maximum amount allowed pursuant to 31 U.S.C. § 3730(d) of the False Claims Act and/or any other applicable provision of law;

C. Relator be awarded all costs and expenses of this action, including attorneys' fees as provided by 31 U.S.C. § 3730(d) and any other applicable provision of the law;

D. Relator be awarded such other and further relief as the Court may deem to be just and proper.

As to the State Claims:

E. Relator and each named State Plaintiff be awarded statutory damages in an amount equal to three times the amount of actual damages sustained by each State as a result of Defendants' actions, as well as the maximum statutory civil penalty for each violation by Defendant within each State, all as provided by:

i. Cal. Gov't Code § 12651;

ii. Cal. Ins. Code § 1871.7(b);

iii. Colo. Stat. Ann. § 25.5-4-304;

iv. Conn. Gen. Stat. § 4-275;

v. 6 Del. C. § 1201;

vi. Fla. Stat. Ann. § 68.082;

vii. Ga. Code. Ann. § 49-4-168.1;

viii. Haw. Rev. Stat. § 661-21;

ix. 740 Ill. Comp. Stat. Ann. § 175/3;

x. 740 Ill. Comp. Stat. § 92/5(b);

xi. Ind. Code § 5-11-5.7-2;

xii. Iowa Code § 685.2;

xiii. La. Rev. Stat. § 46:438.6;

xiv. Mass. Gen. Laws Ch. 12 § 5B;

xv. Mich. Comp. Laws § 400.612;

xvi. Minn. Stat. § 15C.01;

xvii. Mont. Code Ann. § 17-8-403;

xviii. Nev. Rev. Stat. Ann. § 357.040;

xix. N.H. R.S.A. §167:61-b(I);

xx. N.J.S.A. 2A:32C-3;

xxi. N.M. Stat. Ann. § 27-14-4;

xxii. N.Y. Fin. Law § 189.1(g);

xxiii. N.C. Gen. Stat. § 1-607;

xxiv. 63 Okla. St. Ann. § 5053.1;

xxv. R.I. Gen. Laws 9-1.1-3;

xxvi. Tenn. Code Ann. § 71-5-182;

xxvii. 32 V.S.A. § 631;

xxviii. Va. Code Ann. § 8.01-216.3;

xxix. Wash. Rev. Code Ann. § 74.66.020;

xxx. 32 L.P.R.A § 2934(1)(d);

xxxi. D.C. Code Ann. § 2-308.14; and

F. Relator and Plaintiff State of Texas be awarded two times the amount of any payment or the value of any monetary or in-kind benefit provided under the Texas Medicaid program, directly or indirectly, as a result of the unlawful acts described above, plus interest on the amount of the payment or the value of the benefit, as well as the maximum statutory civil penalty for each violation of Tex. Hum. Res. Code Ann. § 36.052;

G. Relator be awarded his relator's share of any judgment to the maximum amount provided pursuant to:

i. Cal. Gov't Code § 12651(g)(2);

ii. Cal. Ins. Code § 1871.7;

iii. Colo. Stat. Ann. § 25.5-4-306;

iv. Conn. Gen. Stat. §§ 4-278, 4-279;

v. 6 Del. C. § 1205;

vi. Fla. Stat. Ann. § 68.085;

vii. Ga. Code. Ann. § 49-4-168.2(i);

viii. Haw. Rev. Stat. § 661-27;

ix. 740 Ill. Comp. Stat. Ann. § 175/4(d);

x. 740 Ill. Comp. Stat. Ann. § 92/25;

xi. Ind. Code § 5-11-5.7-6;

xii. Iowa Code § 685.3;

xiii. La. Rev. Stat. § 46:439.4;

xiv. Mass. Gen. Laws Ch. 12 § 5F;

xv. Mich. Comp. Laws § 400.610a;

xvi. Minn. Stat. §§ 15C.01, *et seq.*;

xvii. Mont. Code Ann. § 17-8-410;

xviii. Nev. Rev. Stat. Ann. § 357.210;

xix. N.H. R.S.A. § 167:61-e;

xx. N.J.S.A. 2A:32C-7;

xxi. N.M. Stat. Ann. § 27-14-9;

xxii. N.Y. Fin. Law § 190.6;

xxiii. N.C. Gen. Stat. § 1-610;

xxiv. 63 Okla. St. Ann. § 5053.4;

xxv. R.I. Gen. Laws 9-1.1-4;

xxvi. Tenn. Code Ann. § 71-5-183;

xxvii. Tex. Hum. Res. Code Ann. § 36.110;

xxviii. 32 V.S.A. § 635;

xxix. Va. Code Ann. § 8.01-216.7;

xxx. Wash. Rev. Code Ann. § 74.66.070;

xxxi. 32 L.P.R.A § 2934b,

xxxii. D.C. Code Ann. § 2-308.15; and

H. Relator be awarded all costs and expenses associated with each of the pendent State FCA and insurance fraud claims, plus attorney's fees as provided pursuant to:

i. Cal. Gov't Code § 12651(g)(8);

ii. Cal. Ins. Code § 1871.7;

iii. Colo. Stat. Ann. § 25.5-4-306;

iv. Conn. Gen. Stat. §§ 4-278, 4-279;

v. 6 Del. C. § 1205;

vi. Fla. Stat. Ann. § 68.086;

vii. Ga. Code. Ann. § 49-4-168.2(i);

viii. Haw. Rev. Stat. § 661-27;

ix. 740 Ill. Comp. Stat. Ann. § 175/4(d);

x. 740 Ill. Comp. Stat. Ann. § 92/25;

xi. Ind. Code § 5-11-5.7-6;

xii. Iowa Code § 685.3;

xiii. La. Rev. Stat. § 46:439.4;

xiv. Mass. Gen. Laws Ch. 12 § 5F;

xv. Mich. Comp. Laws § 400.610a;

xvi. Minn. Stat. § 15C.01, *et seq*.;

xvii. Mont. Code Ann. § 17-8-410;

xviii. Nev. Rev. Stat. Ann. § 357.180;

xix. N.H. R.S.A. § 167:61-e;

xx. N.J.S.A. 2A:32C-8;

xxi. N.M. Stat. Ann. § 27-14-9;

xxii. N.Y. Fin. Law § 190.7;

xxiii. N.C. Gen. Stat. § 1-610;

xxiv. 63 Okla. St. Ann. § 5053.4;

xxv. R.I. Gen. Laws § 9-1.1-4;

xxvi. Tenn. Code Ann. § 71-5-183;

xxvii. Tex. Hum. Res. Code Ann. § 36.110;

xxviii. 32 V.S.A. § 635;

xxix. Va. Code Ann. § 8.01-216.7;

xxx. Wash. Rev. Code Ann. § 74.66.070;

xxxi. 32 L.P.R.A § 2934a(4);

xxxii. D.C. Code Ann. § 2-308.15; and

I. Defendants cease and desist from further violations of the FCA, various state FCAs as set forth above, and the California Insurance Frauds Prevention Act and the Illinois Insurance Claims Fraud Prevention Act;

J. Relator and State Plaintiffs be awarded pre- and post-judgment interest on the awards ordered herein; and

K. Relator and State Plaintiffs be awarded such further relief as the Court deems appropriate and just.

As to the State Insurance Fraud Claims:

L. Relator and the States of California and Illinois be awarded statutory damages in an amount equal to three times the amount of actual damages sustained by each State and the as a result of Defendants' actions, as well as the maximum statutory civil penalty for each violation by Defendants;

M. Relator be awarded his relator's share of any judgment to the maximum amount provided by the California Insurance Frauds Prevention Act and the Illinois Insurance Claims Fraud Prevention Act;

N. Relator be awarded all costs and expenses associated with each state claim, plus attorney's fees as provided pursuant to the California Insurance Frauds Prevention Act and the Illinois Insurance Claims Fraud Prevention Act;

O. Defendants cease and desist from further violations of the California Insurance Frauds Prevention Act and the Illinois Insurance Claims Fraud Prevention Act;

P. Relator and the States of California and Illinois be awarded pre- and post-judgment interest on the awards ordered herein; and

Q. Relator and the States of California and Illinois be awarded such further relief as the Court deems appropriate and just.

X. DEMAND FOR JURY TRIAL

Pursuant to Federal Rule of Civil Procedure 38(a), Relator hereby demands a trial by jury as to all issues so triable.

Dated: November 24, 2021

Respectfully submitted,

By: */s/Robert A. Magnanini*
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CERTIFICATION PURSUANT TO L. CIV. R. 11.2

I certify that, to the best of my knowledge, this matter is not the subject of any other action pending in any Court or any pending arbitration or administrative proceeding.

STONE & MAGNANINI LLP

Attorneys for Relator

By: */s/ Robert A. Magnanini*
Robert A. Magnanini

Dated: November 24, 2021